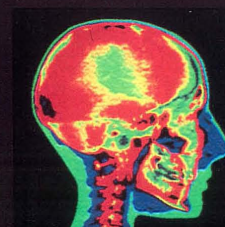


Bioengineering and Rehabilitation

Windows of Opportunity
Past, Present and Future



NASA



Bioengineering and Rehabilitation

A Review of Progress by—

Terrestrial Applications Program
Technology Utilization Division

Nasa- EP-216
1985

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NASA
National Aeronautics and
Space Administration

The American space program draws on the best scientific and engineering talent in this country. The combined effort of our Federal, academic, and industrial team members has produced an expanding technology base so powerful that many formidable engineering challenges faced by man are being solved dramatically and expeditiously.

It is in the best interest of the United States to use its space technology in as broad a manner as possible. Every citizen benefits directly from our national investment in space activities. Indeed, advances in metallurgy and in the electronic and computer sciences benefit many facets of life.

The National Aeronautics and Space Administration is particularly proud of the manner in which the technology of the aeronautics and space program is being applied to specific problems in medicine and physical rehabilitation. Our technology transfer process has contributed significantly to recent advances in the biomedical sciences.

This book has a two-fold purpose—to inform and to stimulate. First, we want to show the breadth of the problems in medicine and rehabilitation which are benefiting through use of technology from our aeronautics and space program. Second, we want to encourage more individuals and industries to participate in our technology transfer process and to apply this technology to an even wider range of medical problems.

Isaac T. Gillam IV
*Assistant Administrator
for Commercial Programs*

*“... for the benefit of all
mankind”*

These words from the National Aeronautics and Space Administration Space Act of 1958 serve as a mandate for the technology transfer and utilization efforts of NASA. For a quarter of a century, NASA has operated at the pinnacle of high technology within the Federal establishment. It could not be otherwise as we address the enormous challenge of moving men and machines at an increasing pace into a multitude of space missions. The success of these missions—ranging from manned exploration of the moon to servicing of orbital satellites—is well known. The advanced technologies developed to support these missions are not as well known but are every bit as impressive. Materials that withstand the radical temperature extremes in space, electronic switches which operate at distances of millions of miles, valves functioning with unbelievable precision and reliability—all flow from NASA Research and Development programs.

The National Aeronautics and Space Administration is committed to insuring that its technological achievements extend beyond the direct needs of space missions to the general benefit of all citizens. The transfer of aeronautics and space technology to biomedical needs is an excellent example. This report describes a number of efforts in which this technology, as provided through the NASA Technology Utilization activities and its academic and industrial team members, is offering real time improvement in the quality of life to those citizens with medically related problems.

Raymond P. Whitten
*Chief, Terrestrial Applications,
Technology Utilization Division*

Windows Of Opportunity . . . Past, Present and Future

Through twenty-five years of research and technology development in a variety of fields, the National Aeronautics and Space Administration has amassed an array of technologies to meet its many mission needs and which, in turn, can be well applied to Earthly problems. These advanced technologies cover such fields as materials, electronics, computer science, biomedicine and robotics. Of particular interest here is the process whereby NASA technology is transferred into medical engineering and the development of systems to support the ill, handicapped and infirm.

NASA is committed to helping industrial organizations, academic institutions, and public sector organizations make effective use of the technologies developed under NASA auspices. A significant part of the NASA organization and resources is committed to the technology transfer process.

NASA's approach is to create windows of opportunity that enable private organizations to develop marketable products through application of NASA-developed technology. Each window focuses upon possible matches between a problem requiring a technical solution and specific, available technologies from NASA. This report describes some successes in the "Windows of Opportunity" Program—those in the past where the transfer is complete and products are commercially available, those in the present which are in the process of transfer, and those in the future for which initial concepts and development efforts are being formed at this time.

The Organization

The key components in the transfer of NASA technology to meet biomedical needs include:

Terrestrial Applications.

A branch of the Technology Utilization Headquarters activity within the National Aeronautics and Space Administration, which establishes policy for the biomedical transfer process, allocates resources and coordinates activities among the operating units. This office serves as the main link in establishing a working relationship with other Federal agencies such as the Veterans Administration and the National Institutes of Health. Cooperation with these and other Federal agencies is most important in the transfer process.

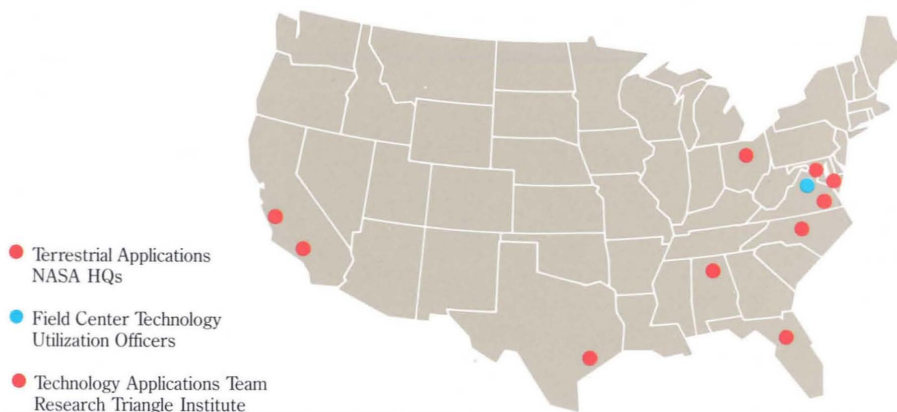
Technology Utilization Officers.

These individuals manage the participation of NASA Centers in all technology utilization activities. They participate in the identification of problems and survey NASA scientists and engineers for technology and expertise that can be applied to the problem. They also coordinate contracting activities with industry as the technology is being prepared for evaluation and potential commercialization.

Technology Applications Team.

This team, located at the Research Triangle Institute, North Carolina, and supported by the National Aeronautics and Space Administration, aids NASA Headquarters in the coordination of biomedical transfer, works with NASA Field Center personnel on specific projects, and provides liaison support with other federal agencies, state organizations and industry as required. Program methodology and activities of the technology applications team are to (1) identify problems through interaction with clinicians and medical researchers, (2) identify and screen applicable NASA technology that meets the medical needs, (3) develop commercialization strategies, and (4) transfer potential medical innovations to private industry or institutions for final development and marketing.

Private organizations and individuals may contact the National Aeronautics and Space Administration concerning any biomedical topic which might benefit through the utilization of aeronautics and space technology. The following map shows the general location of points of contact. More detailed information concerning the organization and its additional accomplishments may be found in a publication entitled "Spinoff," published annually by the National Aeronautics and Space Administration.



Technologies That Have Transferred

Life for the medically afflicted, the handicapped and the elderly is being made better today through the use of new medical systems and therapeutic procedures which incorporate advanced technologies initially developed for the Aeronautics and Space Program.

Examples of successful technology transfer include:

1	Wheelchair Development	6
2	Programmable Pacemakers	8
3	Cardiology Mannequin	10
4	Advanced Defibrillator Monitoring System	11
5	Human Tissue Stimulator	12
6	Automicrobic System (AMS)	13
7	Lixiscope	14
8	Spacestat Blood Analyzers	16
9	Aseptic Fluid Transfer System	17
10	Chromosome Analysis	18
11	Muscle Biopsy	19
12	Ultrasound Imaging	20
13	Eyetracker and Stabilized Laser Photocoagulator	22
14	Gait Analysis	23

The ability to move freely is the essence of life in modern society. A special burden for the handicapped is lack of mobility. To ease this burden, wheelchairs have long been in use. At this time, some 700,000 people in the United States rely on wheelchairs for mobility.

Wheelchairs have a variety of designs developed to meet different needs. There are depot wheelchairs for use in airports and other public places, hospital wheelchairs designed to meet special requirements (I.V. bottles, leg casts, etc.), drugstore wheelchairs for short-term users, prescription wheelchairs for chronic disabilities, and sports wheelchairs. Power is provided by an attendant, the handicapped person, or a separate power source such as batteries.

Designers are drawing on today's advanced technologies to meet the many requirements of improved wheelchairs. One requirement is for better strength. Engineers at the NASA Langley Research Center are working with scientists at the University of Virginia Rehabilitation Engineering Center in a program to develop computer-

aided design procedures for wheelchairs. A structural analysis of wheelchairs based on a finite element computer program is being utilized to identify critical areas of stress buckling and vibration. With this system, a sports wheelchair has been modeled using a particular load distribution and set of structural constraints. Results will lead to stronger wheelchairs with better ride quality.

Size and weight also present a problem. Conventional-use wheelchairs fabricated from metallic tubular elements are frequently heavy and difficult to handle—especially during storing and retrieving from automobiles. In addition, the metallic wheelchairs are subject to corrosion and fatigue damage during normal use. These difficulties have been eased recently through efforts of a multi-organizational cooperative program leading to the development of a lightweight, folding, conventional wheelchair constructed largely from advanced composite materials.

A prototype composite chair was designed by the University of Virginia Rehabilitation Engineering Center in

an effort coordinated by NASA's Research Triangle Institute Technology Applications Team and with support from the National Institute of Handicapped Research and the NASA Langley Research Center. The prototype is made of Langley-furnished composite materials and weighs only 24 pounds, about one-half the weight of a standard wheelchair. It can support a 200-pound person, is easily folded, and can be stowed with little effort.

The composite chair makes extensive use of modern aerospace materials which offer very high strength and low weight. This development program exemplifies the manner in which aeronautics and space technology is being used to improve the quality of modern life.



The wheelchair of yesteryear



A prototype wheelchair made of composite materials offering exceptional strength and light weight.



A prototype lightweight wheelchair designed especially for airline use. The design draws on aerospace technologies for structural analysis and materials engineering.

Programmable Pacemakers

The development of cardiac pacemakers is an outstanding example of the manner in which biomedical technology can produce a real improvement in the lifestyle of the ill and handicapped. The remarkable medical achievements seen in this and other fields during the past twenty years are intimately related to progress in the aerospace sciences. The cardiac pacemaker project also illustrates the manner in which Federal agencies, academic institutions, and industrial organizations can establish a productive and synergistic working relationship.

Diseases of the heart remain the leading cause of death in the United States, although the picture improves every year. Many fatal heart attacks result from a malfunction of the neuroelectric control system that regulates the periodic contraction of heart muscles. With early detection of such malfunction, a pacemaker can be implanted to generate an electrical pulse that controls heart muscle contractions.

Early pacemakers, developed through a NASA Goddard Space Flight Center program on hybrid circuit technology, used mercury-zinc batteries which were heavy and shortlived. Sur-

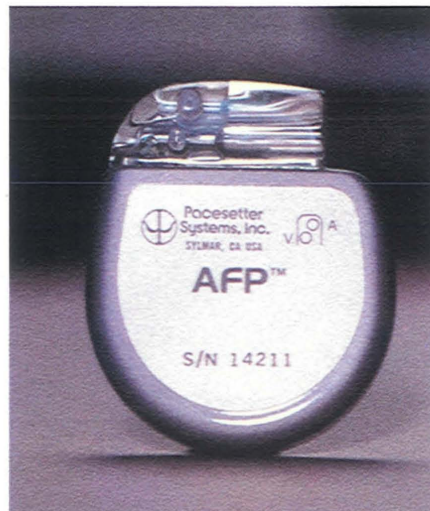
gical replacement of the battery was necessary every eighteen months or so. This picture changed in the late 1960s when the Johns Hopkins University Applied Physics Laboratory proposed a recharging concept based on electromagnetic transmission through the intact skin. Rechargeable batteries of the type used in satellites could solve the pacemaker short life problem.

In 1973, Pacesetter Systems, Inc. of Sylmar, California, working with the Applied Physics Laboratory and the Medical Institutions of the Johns Hopkins University, perfected the first commercially available model of a rechargeable pacemaker. This employs a hermetically sealed rechargeable unit containing a single-cell nickel-cadmium battery such as those used in most satellites. Today, an even more advanced battery based on lithium electrochemistry is used. This has exceptionally high energy densities and a very low self-discharge rate.

Pacemaker technology had another advance in 1979 when a programmable unit was introduced. Pacesetter Systems developed Programalith, a system with two-way communications capability based on technologies

developed by NASA to send coded instructions to unmanned satellites. The Programalith system allows a physician to communicate with a patient's pacemaker by means of wireless telemetry signals. Where earlier pacemakers delivered a fixed type of stimulus once implanted, the Programalith system can be "fine-tuned" to meet each patient's individual needs. As many as six heart stimulating functions; for example, pulse rate, amplitude, and width, can be adjusted as necessary. When reprogramming is complete, the system sends back a copy of the new settings from which a permanent record can be made.

Recent technology developments by Pacesetter Systems have been directed toward an Advanced Function Pacer, which offers an implantable device smaller than any Programalith unit and incorporates substantially increased programming capability. This system is capable of sensing and stimulating either or both chambers of the heart and offers both better control over and monitoring of heart function.



The Advanced Function Pacemaker II 283 by Pacesetter Systems, Inc. features 14 programmable parameters, is 10mm across, and weighs 50 grams.



PACEMETER SYSTEMS INC.
Version 1.5

DATE: FEB 16, 1984 4:10 PM

MODEL: 283 SERIAL: 1271

PATIENT: _____

PHYSICIAN: _____

----- PROGRAMMED PARAMETERS -----

MODE DD%
RATE 70 PPM

VENTRICULAR CHANNEL:
REFRACTORY 250 MSEC
PULSE WIDTH 0.6 MSEC
PULSE AMPLITUDE 5.0 VOLTS
SENSITIVITY 2.0 MVOLT

ATRIAL CHANNEL:
REFRACTORY 250 MSEC
PULSE WIDTH 0.6 MSEC
PULSE AMPLITUDE 5.0 VOLTS
SENSITIVITY 1.0 MVOLT

AV INTERVAL 165 MSEC
MAX. TRACK RATE 130 PPM
BLANKING PERIOD 13 MSEC
MAGNET: ON

----- MEASURED DATA -----

PACEMAKER RATE 70.0 PPM
MAGNET RATE 80.0 PPM

CHANNEL MEASUREMENTS:

	VENTRICLE	ATRIUM	
PULSE VOLTAGE	4.9	4.9	VOLTS
PULSE CURRENT	9.4	9.6	MAmps
PULSE ENERGY	31	29	μJoules
PULSE CHARGE	7	6	μCoulombs
LEAD IMPEDANCE	521	510	OHMS

BATTERY DATA: (W.G.8074 - NOM.2.3 AHR)
IMPEDANCE 1.0 KOHMS
VOLTAGE 2.71 VOLTS
CURRENT 28 μAMPS

----- TEST RESULTS -----

VENTRICULAR R-WAVE AMPLITUDE: 7.0 MVOLTS
SAFETY MARGIN: 3.5:1

VENTRICULAR CAPTURE THRESHOLD: 1.5 VOLTS
AT 0.6 MSEC PULSE WIDTH

ATRIAL P-WAVE AMPLITUDE: 2.5 MVOLTS
SAFETY MARGIN: 2.5:1

ATRIAL CAPTURE THRESHOLD: 1.8 VOLTS
AT 0.6 MSEC PULSE WIDTH

Stored Telemetry Data

Programmable Parameters

Lead Impedance

Test Results

Programmed Telemetry Data

Measured Telemetry Data

Pulse Output Data

Battery Data

Printed record from Advanced Function
Pacemaker.

The evaluation of cardiovascular disease relies heavily on the physician's examination. The bedside findings from this examination allow initial diagnoses among a variety of heart conditions and guide the use of complex laboratory procedures. The development of effective diagnostic skills, however, requires a physician first to see patients with the full spectrum of heart disease at various stages in development. Second, the examination skills must be practiced routinely and repetitively. To achieve this with actual patients is difficult and expensive. The Cardiology Patient Simulator, "Harvey," capable of simulating a wide range of heart conditions, represents a cost-effective means of meeting these training objectives.

The cardiology mannequin is capable of simulating virtually unlimited cardiac disease states. Synchronized bilateral arterial (carotid, brachial, radial, and femoral) and jugular venous pulsations, precordial movements, respiration, blood pressure, and auscultation

in the four classic acoustic areas are exactly simulated. Complex acoustic events vary with respiration when appropriate. Slide programs display background data for each disease state to increase the realism and effectiveness of training.

The Cardiology Patient Simulator program has been guided by Dr. Michael S. Gordon, Professor of Cardiology at the University of Miami (Florida) School of Medicine. Physicians and scientists from other medical centers, including the University of Arizona, Duke University, Emory University, the University of Florida, Georgetown University, the Mayo Clinic, and the University of Nebraska, as well as the National Heart, Lung and Blood Institute have participated in the program. Industrial organizations and NASA, which provided display technology for the presentation of training materials, also participated.

Harvey is becoming an accepted instructional system. An evaluation under the auspices of the National Heart,

Lung and Blood Institute found that students who trained with this system scored higher on tests of cardiology knowledge and showed improved performance when examining actual patients.

There are currently eighteen Cardiology Patient Simulators in use, including one in Thailand and one in Japan. "Harvey" is used to instruct nurses, fourth-year medical students, and for other educational purposes. The production of the current model (third generation) is being done through the University of Miami in Florida.



Advanced Defibrillator Monitoring System

Victims of heart attacks require immediate and proper care. If cardiac arrest occurs when no one else is present, it is fatal. The prospects for recovery are good, however, if treatment is given promptly and circulation maintained until the victim reaches a hospital. If the attack occurs when the patient is in a hospital, prospects are even better. If cardiac arrest is caused by ventricular fibrillation, the heart-beat often can be restored with a defibrillator, an apparatus that briefly passes an electric current through the heart.

The defibrillator sends an electric shock to the heart via two metal plates positioned properly on the chest wall. This method of restarting a stopped heart mimics a natural process in which impulses from the right atrium spread through the heart in the normal beating pattern of the heart. Once the defibrillator has imposed a normal pattern of electrical activity, the pattern usually will be sustained by the heart. For it to be successful, however, the

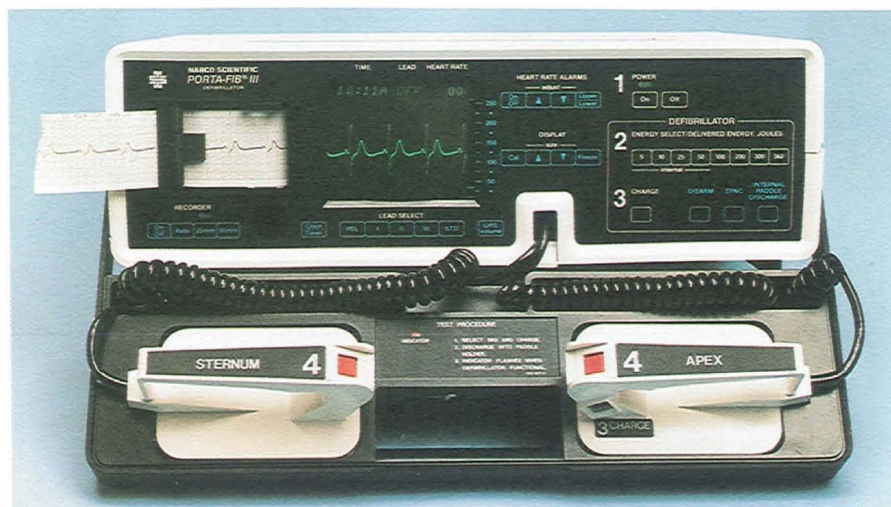
defibrillator must be readily accessible and put into immediate use.

The advanced defibrillator monitoring system is light-weight, portable and easy to operate. It combines the defibrillator contacts (paddles) with a microprocessor-based monitoring system to display both treatment and patient information. The advanced defibrillator monitoring system is an outgrowth of an earlier NASA project known as the Physician's Black Bag, a portable monitoring/treatment unit developed for the Johnson Space Center by Telecare, Inc., known following acquisition as Narco Bio-Systems, in Houston, Texas.

The advanced defibrillator monitoring system is designed principally for use in a hospital environment. It incorporates sealed membrane key-switch controls in a work station layout. Each emergency operating step is indicated in numerical sequence for quick application, even with inexperienced users. There is a built-in annotating recorder and clock for complete documentation

of its use in a fibrillation event.

This system, although designed for hospital application, now is being considered as part of a prototype life support module for possible application aboard future Space Shuttle flights. As the population of Space Shuttle crewmembers becomes more diverse, the possibility of a cardiac episode must be considered. Appropriate treatment equipment must be available as part of the on-board medical system.



Neuromuscular difficulties, in particular the problem of chronic pain, often can be helped by electrical stimulation of nerve and muscle tissue. Chronic pain from arthritis, rheumatism, and other disorders affects at least ten percent of the population. Several thousand of these obtain regular relief through electrical stimulation procedures. Devices in present use, however, require an external power source and a transmitting coil taped to the skin twenty-four hours a day. A device of this type is uncomfortable, inconvenient, and generally unreliable, often with a greater than ninety percent annual failure rate.

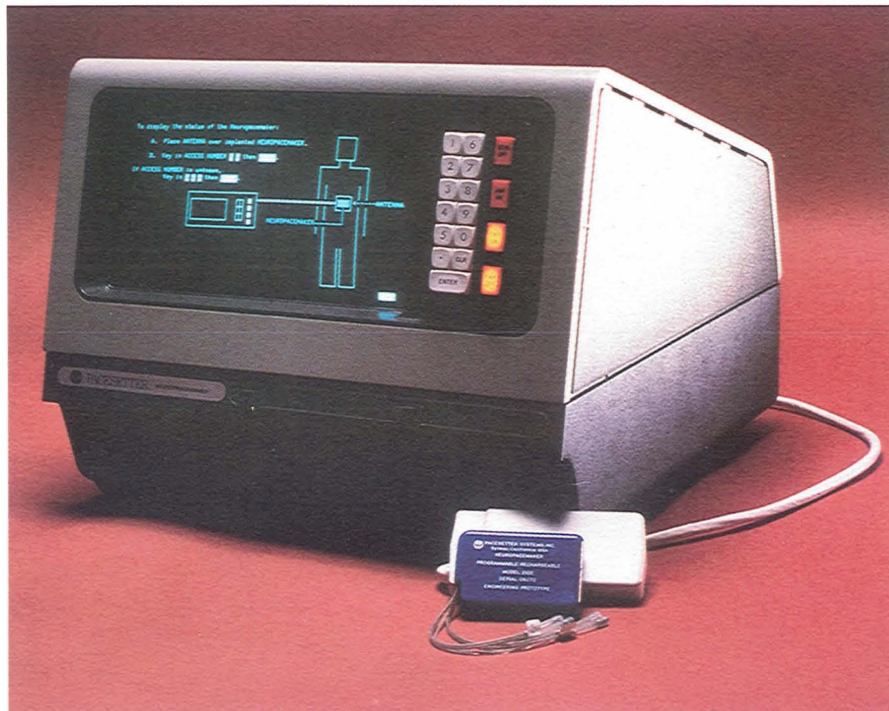
Pacesetter Systems, Inc., of Sylmar, California, working with the Applied Physics Laboratory of The Johns Hopkins University, has developed the Human Tissue Stimulator. This is an implantable device offering a solution for most of the problems found with earlier stimulation systems. The new device is based on technology developed at NASA Goddard Space Flight

Center and employed in the Small Astronomy Satellite-3. The Human Tissue Stimulator incorporates a nickel cadmium battery, telemetry and command systems technologies derived from those used with the satellite and reduced to microminiature proportions. The implantable element is the size of a deck of cards.

The first two stimulator units to be implanted were quite successful. In one, a patient with severe involuntary movement disorders from multiple sclerosis achieved complete control over the tremors. In the second, a patient who suffered excruciating pain from a wrist injury incurred in a fall reported immediate relief from the pain. Based on the success of these trials, Pacesetter Systems is moving to commercial production.

The field of electrostimulation is advancing to encompass complex neurological disorders. Pacesetter Systems now has developed the implantable Neurolith 601 as a promising device for the treatment of the

spasticity of cerebral palsy and for the suppression of epileptic seizures. The device has been shown to be safe and effective in over one hundred cerebral palsy patients. The next phase will be the development of fully programmable neuropacers adjustable through microprocessor technology to the changing needs of the individual patient.



The Pacesetter Neuropacer with its programmer/monitor.

AutoMicrobic System (AMS)

Any innovation that offers reduced hospital stay time is a welcome advance in health care service because of the potential for saving money for both the patient and the hospital. One such time-saving innovation, based on aerospace technology, is an automated system used by hospital laboratories to detect and identify microorganisms that cause infection. It has the additional capability to test these organisms to determine which treatment would be most effective in eradicating them.

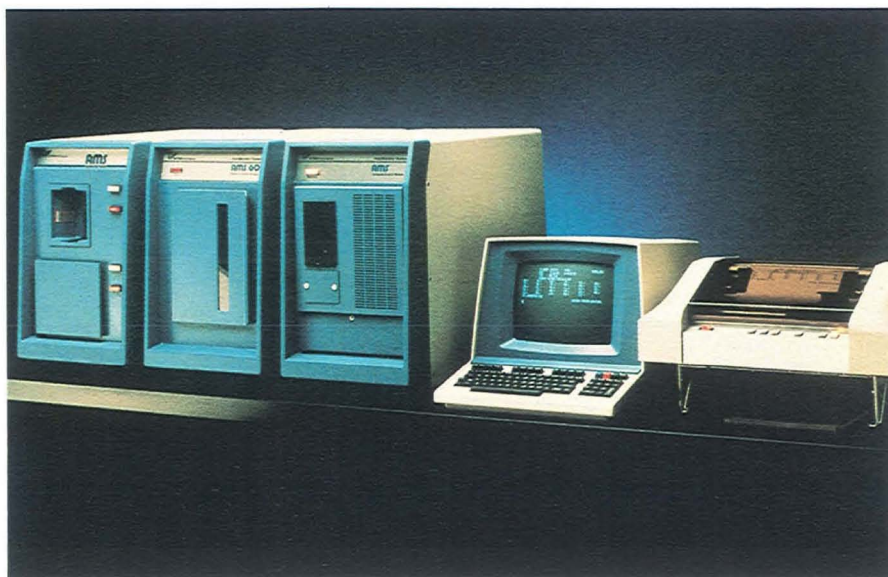
Vitek's AutoMicrobic System (AMS) is the product of years of research and development by McDonnell Douglas Corporation. The project originated in a NASA-sponsored study aimed at developing a fully-automated microbial detection and identification system for the space program. AMS is now commercially available through Vitek Systems, Inc., Hazelwood, Missouri, a McDonnell Douglas subsidiary.

The traditional method of testing for harmful organisms or pathogens re-

quires several steps. First, specimens of body fluid—urine, for example—or swabs from infected areas of the body—throat, for example—are prepared in cultures. These cultures are, in effect, "food" for specific types of microbes. Next, the cultures are incubated for two to three days and studied for cell growth. From such study microbiologists then can determine the presence of disease-producing organisms and identify the pathogens.

The AMS does the same job quicker. Specimens from patients are prepared in culture in miniaturized form. Over 30 tests can be done simultaneously on the same microorganism in a kit approximately the size of a playing card. During an incubating cycle in the AMS, an electro-optical scanner studies each kit once an hour. Changes in cell growth are monitored and analyzed by computer. The AMS automatically reports its findings after sufficient data are collected. This information is printed and displayed on a CRT screen.

The AutoMicrobic System enables the microbiology laboratory to furnish guidelines to a patient's doctor for antimicrobial therapy the day after a specimen is collected. This amounts to a time saving of 50 to 80 percent over standard laboratory methods. The system also minimizes human error, reduces technician time, and increases laboratory output, for the AMS can handle up to 240 patient specimens at one time. Of greatest importance to the patient is shorter stay in the hospital due to faster analysis of the infection and earlier treatment.



Aerospace technology has led to the development of a portable X-ray image intensifier called Lixiscope which promises to be useful in a number of applications in medical and dental fluoroscopy and intensifier-assisted radiography, making it possible to use a weak radiation source and potentially reducing the dosage to the patient and radiologist. Such a combined radiation source and image intensifier is so compact that for certain fluoroscopic examinations a truly portable system can be brought to the homes of bedridden and handicapped patients.

The Lixiscope—which stands for Low Intensity X-ray Imaging SCOPE—evolved out of the technology intended to observe celestial X-ray objects from orbiting satellites. In X-ray astronomy the intensity of the radiation received is extremely low. Astronomers sometimes want to observe objects so faint that the imaging system must respond to only one photon of radiation at a time. In the laboratory of NASA's Goddard Space Flight Center, scientists developed an image intensifying device that capitalized both on the high efficiency of existing rare-Earth phosphor screens (which detect and convert X-rays into visible light) and the high visible-light gain of cer-

tain night vision image intensifiers in amplifying the resulting light.

Because the energy range of X-rays used in medical diagnostics is similar to the energy range of celestial X-ray objects, such a low-intensity X-ray imaging system is also well suited for some medical applications.

The original Lixiscope uses a tiny radioactive source as its supply of X-rays, making it a nearly pocket-size system. However, radioactive sources are unable to supply the ideal energy, intensity, or spectral distribution of X-rays in some applications. For such cases a miniature battery-operated X-ray generator has been developed recently at NASA's Goddard Space Flight Center. With the X-ray generator, the energy, intensity and spectral distribution of X-rays can be adjusted at will. Therefore, in addition to radioactive sources, the miniature X-ray generator should make the Lixiscope even more versatile in a large variety of medical and industrial applications.

Currently, Lixiscopes with radioactive sources are being manufactured by Lixi, Inc., Downers Grove, Illinois. A number of companies have also obtained licenses from NASA to manufacture Lixiscopes with the miniature X-ray generator.



Space Stat Blood Analyzers

Regulation of blood electrolytes is crucial for well being. High blood pressure, dehydration, urine loss, diarrhea, kidney failure, diabetic coma and certain types of brain injury all affect sodium levels. Potassium levels can be critical since abnormal amounts can cause disturbances in the cardiovascular, nervous, and muscle systems. Ionic calcium regulation is needed for blood coagulation, nerve junction and normal skeletal and cardiac muscle contraction. As part of a program to develop techniques for monitoring electrolytes of astronauts on long flights, NASA contracted with ORION Research of Cambridge, Massachusetts, to produce compact analyzers. The traditional method of electrolyte measurement at the time required flammable gases which could not be used on space flights. ORION solved the problem by developing electrode-

based devices which operated well under space conditions.

Included among the variety of blood testing instruments brought about by space research are electrode-based electrolyte analyzers, notably sodium/potassium and ionic calcium analyzers.

As a spin-off of that early work, ORION manufactured two devices that simplified electrolyte analyses in clinical laboratories. The Space Stat-20 calcium analyzer is still being distributed by ORION, but its companion sodium/potassium analyzers, called Space Stat-30, was replaced in 1982 by Model 1020.

Model 1020 has increased the level of automation in the sodium/potassium measurement through increased use of microcomputers. With virtually no training, almost anyone can run analyses on the instrument. There are no knobs or dials to turn—all operations

can be initiated with a push of one of three buttons (YES, NO, ?). Only 100 microliters of whole blood are required for a complete analysis. Results are displayed in less than one minute.

The instrument fits in a foot of space and is portable. In addition to being used in traditional clinical laboratories and surgical rooms, Model 1020 is making sodium/potassium analyses routine in doctors' offices, small laboratories, ambulances and mobile military vehicles.



Space Stat Model 1020 Blood Analysis System.

Aseptic Fluid Transfer System

Many fluid transfer processes must be accomplished without contamination. The purity of liquids is a special concern during the transfer of fluids into the human body. At this time, transfer systems used by blood banks do not ensure sterility. For this reason, the Food and Drug Administration has ruled that blood which is frozen and stored, once thawed, must be transferred within 24 hours or discarded. The Aseptic Fluid Transfer System might well remove this restriction.

NASA has had an ongoing program to ensure the sterilization of spacecraft before launch to the moon and to other planets. Heat-sealed plastic films are used to maintain a sterile environment during last-minute repairs and adjustments prior to launch. This same technology now has been used to provide a means of transferring fluids from one container to another in a sterile manner.

The Aseptic Fluid Transfer System was invented at the NASA Jet Propulsion Laboratory in 1974. It was guided through the technology transfer process and now is licensed to the Health Care Group Laboratories, Inc., of Libertyville, Illinois.

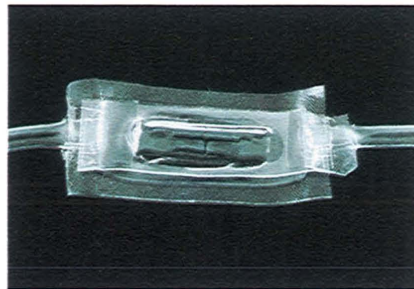
The transfer system uses containers made of two kinds of plastics that melt at different temperatures. Two layers of polyvinyl chloride, which fuses under relatively low heat, enclose a layer of a more heat-resistant plastic in a design allowing the contiguous regions of the two packs to form a common wall. When heat of 200°C is applied with a heat sealer, the connectors are effectively fused, the joining area is sterilized, and an opening is introduced which allows blood to flow from one bag to another. This linking process takes one minute. Any bacteria present on the outer walls of

the containers are killed during the fusing process.

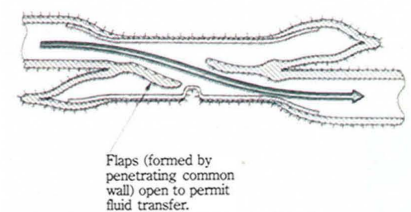
The aseptic fluid transfer system is simple, inexpensive, durable, capable of ensuring sterility, and does not damage red blood cells or blood components during the transfer process. The system appears suitable for a wide array of medical fluid processing functions, including intravenous and dialysis procedures.



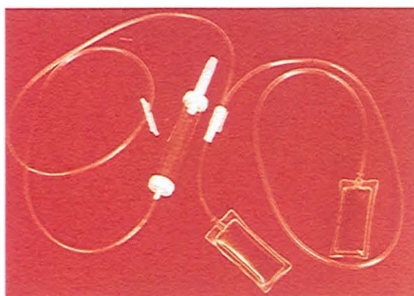
Penetrator



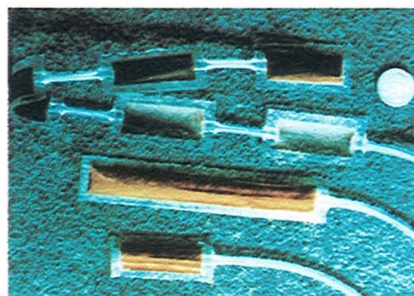
Connector Detail



Schematic



Transfer Set



Multiple Connectors



Donor Receiver

Aseptic fluid transfer system guarantees blood sterility during blood bank transfer processes.

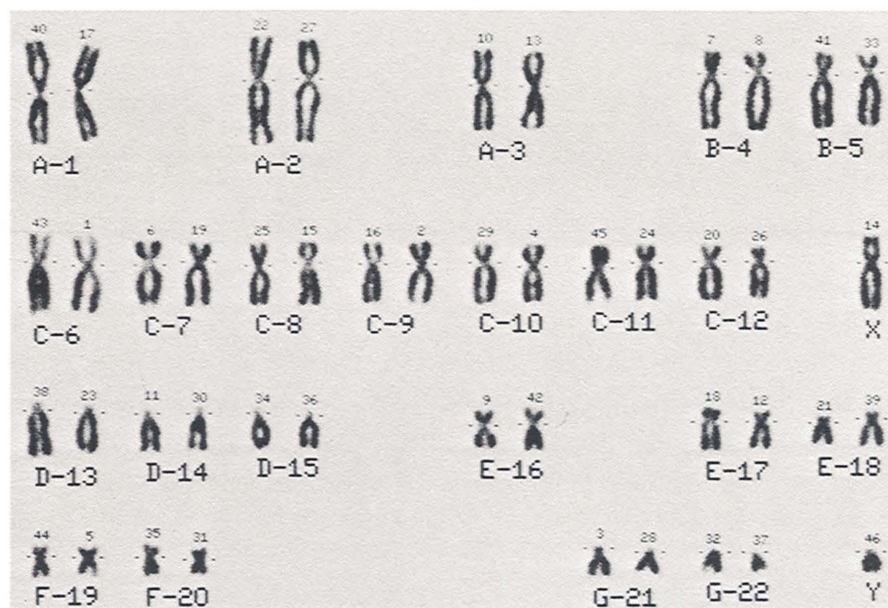
The nucleus of a living cell contains a number of thread-like bodies called chromosomes. Each chromosome, in turn, is made up of genes which contain the "blueprint" of information that transmits hereditary characteristics of the animal or plant from generation to generation. Researchers use this cellular information to study the genetics of cells and organisms. Medical clinicians use it to diagnose (and even prevent) genetic abnormalities in humans. But to be useful to these biomedical professionals, the information about chromosomes contained in a cell must be organized in a structured way. One important organization form is the karyotype, a cataloging of the arrangement of chromosomes, by type, that occur in a cell. The preparation of a karyotype by standard methods from a photograph of the chromosomes within a cell is a laborious procedure that may take a technician several days to complete.

To speed up the preparation of human karyotypes, scientists and engineers at NASA's Jet Propulsion Laboratory developed an Automated Light Microscope System (ALMS) that will

automatically, rapidly and accurately scan a chromosome specimen to measure and classify the chromosomes present. The system uses digital (computer-aided) image processing technology derived from research and development that JPL has carried out in the past in support of NASA automated missions that returned images of Mars, Jupiter, Saturn and other bodies of the solar system.

To be economically feasible for use in a hospital or clinic, an automated chromosome analysis system must consist of two parts: a device that automatically, routinely and quickly scans chromosomes; and another device that automatically, routinely and quickly prepares chromosome specimens for the scanner to use. JPL scientists have fulfilled the first part of this two-device system with their development of the ALMS. Next, this JPL-developed technology was transferred to the City of Hope National Medical Center in Duarte, California, where its biologists developed the second device: a machine that automatically prepares chromosome specimens to be scanned.

Using the ALMS technique, an operator with no special training can perform a karyotyping in 7-16 minutes, depending on the type of specimen. The system is now being used experimentally at the Prentiss Women's Hospital in Chicago to obtain karyotypes of chromosomes obtained from pregnant women through amniocentesis. The potential time and cost savings obtainable by means of this automated technique are clearly great. However, the economic stumbling block to the actual clinical use of an automated chromosome analysis system is the large number of samples needed to keep the machine operating most of the time. If a large-scale, centralized clinical laboratory to conduct automated chromosomal analysis is ever established, the JPL system represents a technology that can be easily updated and put to immediate use.



Homogeneously stained, normal human male karyotype determined by computer.

Skeletal muscles act to move the skeletal structure of the human body and to maintain posture against the pull of gravity. Generally speaking, there are two types of skeletal muscle fiber. "Fast twitch" fibers contract rapidly but tire easily. They predominate in muscles for which sudden exertion is often required, such as calf muscles. "Slow twitch" fibers contract slowly but tire less easily. They are most predominant in muscles requiring endurance, such as back muscles.

About 15 years ago, a simple staining technique was discovered which enables the two types of muscle fibers to be distinguished under a microscope. In cross section, muscle fibers from a biopsy sample form a mosaic pattern of light and dark shapes. Slow fibers are light in color, while fast fibers are dark.

The ATPase-staining technique enabled physicians to diagnose both the type and severity of neuromuscular disease by being able to measure differential change in slow and fast fibers. There was, however, a serious problem. The analysis made by a physician looking through an optical microscope

at stained muscle fibers was subjective and of limited accuracy. A more quantitative and precise analysis method was required.

Scientists at the NASA Jet Propulsion Laboratory became involved in the automated analysis of muscle tissue while studying the observed loss of muscle bulk by humans and animals during space flight. Using a digital image-processing technique to analyze the muscles of rats that had been in space for 18.5 days aboard the USSR Biosatellites, Cosmos 936 and Cosmos 1129, JPL investigators, along with researchers from the University of Southern California, confirmed that there is indeed a reduction in both the size and weight of slow and fast muscle fibers.

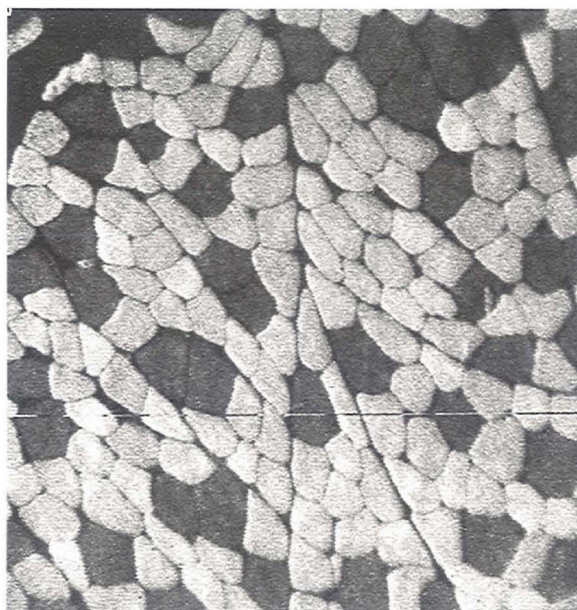
The JPL-developed system uses a computer to aid in carrying out rapid, accurate analysis of muscle samples. The device can measure the area, density, circumference, and intensity of stain of a fiber in about 20 seconds. An advanced version developed by NASA's Applications Engineering Program and the Musclar Dystrophy Association is in use at the University of

California at Los Angeles for basic as well as clinical investigations.

In basic research, the device will address questions such as: What is the nature of normal muscle? What happens to an athlete's muscles as he trains? What happens to the muscles of a patient confined to prolonged periods of bed rest?

In clinical research, the device will address questions such as: What takes place with muscles during prolonged paralysis? Can an early diagnosis be made and progress measured in the treatment of such neuromuscular diseases as myasthenia gravis, muscular dystrophy, and amyotrophic lateral sclerosis (ALS)?

If these questions can be answered successfully, the digital image-processing technique could become a routine tool in the diagnosis, treatment, and evaluation of neuromuscular disease.



Muscle specimen stained to show the mosaic pattern of light and dark shapes representing slow and fast-twitch muscle fibers in cross section.

The cardiovascular system, a network of arteries, veins, and capillaries with the heart serving as the central pump, distributes essential nutrients to cells and removes waste products. Its importance is underlined by the fact that about one-half of all deaths in the U.S. each year are due to failures of cardiovascular system components.

One of the more common problems of the cardiovascular system is atherosclerosis, a progressive build-up of fatty and calcified deposits within arteries. Because this condition narrows the artery, it partly obstructs blood flow and therefore causes an increase in blood pressure. Knowing the condition of a patient's arteries, and being able to track changes in their condition over time, is of prime importance to a physician. The standard technique for visualization of an artery is called angiography. This procedure involves injecting an X-ray-opaque material into the patient and then taking an X-ray photograph of the artery. Although angiography has been used routinely for years, it has significant drawbacks. It uses ionizing radiation; it is invasive (requiring injection of the material into the arteries); and it is not suitable for

exact measurement of arterial blockage.

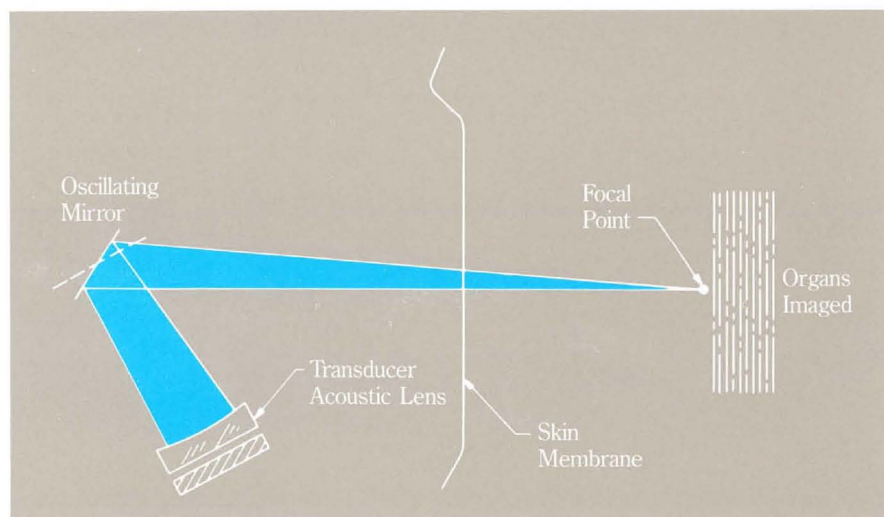
The invention some years ago of the ultrasonic scanner—a device using very high-frequency sound waves to probe and visualize internal bodily structures—was greeted with enthusiasm. It is a risk-free technique requiring no invasive procedures and no ionizing radiation. In addition, it is less expensive than other medical imaging procedures. However, early ultrasonic scanners did not provide very high resolution and contained significant “noise.”

For more than a decade, scientists at NASA's Jet Propulsion Laboratory have been attempting to improve the use of ultrasound as a diagnostic tool in medicine. Conventional ultrasonic instruments are of the pulse-echo type. They transmit a pulse and then “listen” for a return from the target. JPL's researchers realized that this on-off characteristic was the source of the current technology's limitations. Accordingly, they developed an ultrasonic instrument that could do both at once. This “swept-frequency,” time-delay spectroscopy instrument, or TDS, is capable of producing images with sig-

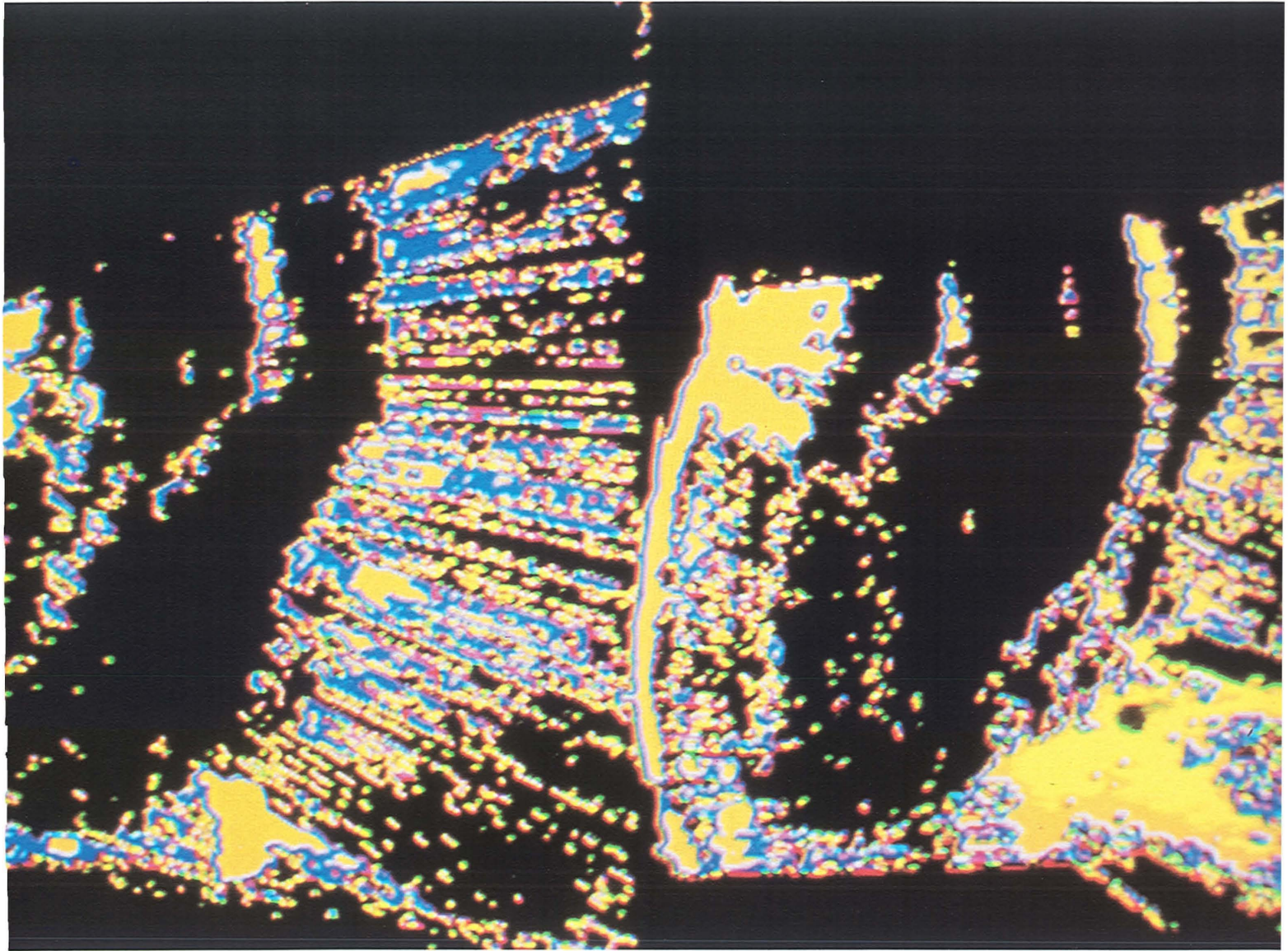
nificantly higher resolution and a better signal-to-noise ratio than the earlier technique.

The JPL-TDS ultrasonic scanner is being used in a study at the Department of Cardiology, University of Southern California School of Medicine, to determine whether an ultrasonic scanner can monitor the development of the slight, subtle atherosclerotic changes. The study involves 85 men who have their shallow-lying carotid (head and neck) arteries scanned five times, with an interval of a month between scans. Several hundred baseline ultrasonic scans now have been completed.

With the improvements brought about by work at JPL, ultrasonic scanning now complements other “high-tech” medical imaging technologies such as computer-assisted tomography (CAT) and nuclear magnetic resonance (NMR). But whereas the TDS ultrasonic scanner costs about \$50,000, CAT and NMR machines cost around \$1.5 million—a major cost savings. With these advantages in view, further improvements to the TDS technology are now the subject of a grant to JPL from the National Institutes of Health.



Operation of Ultrasonic Time-Delay-Spectrometer Scanner developed at JPL.



Eyetracker and Stabilized Laser Photocoagulator

Problems in which the retina of the eye becomes detached or lifts away from its supporting structures are treated by laser photocoagulation. The focused energy of a laser beam "burns" a small part of the retina and causes it to fuse to the rear of the eye, creating a permanent point of attachment. There are two problems, however, which limit the usefulness of the photocoagulation technique. First, a contact lens is placed over the eye of the patient which produces astigmatic distortion with different angles of beam incidence which, in turn, causes the shape of the burn area to vary with retinal location. Second, involuntary eye movements make it difficult to achieve the desired accuracy in locating the burn site. The recently developed eye tracker and stabilized laser photocoagulator offer promise for each of these problems.

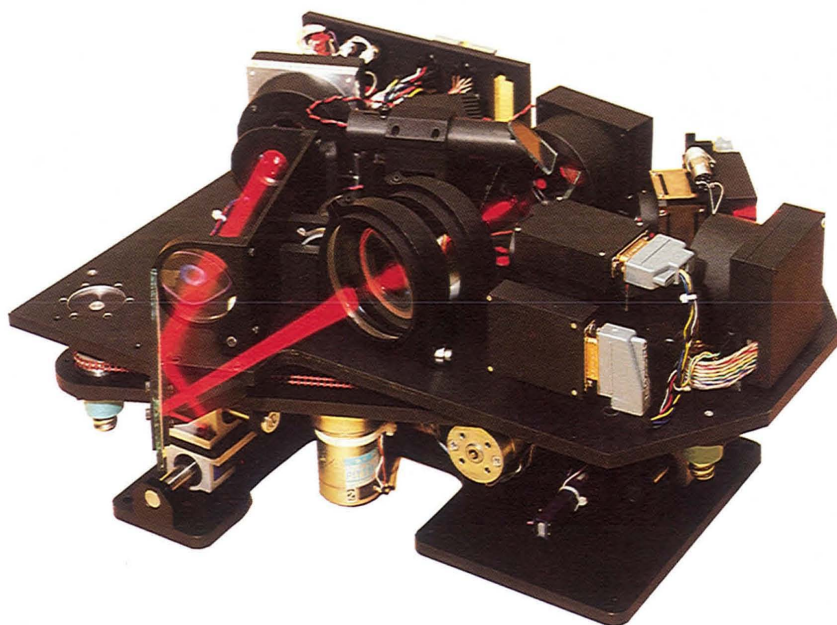
The National Aeronautics and Space Administration in 1965 began support of studies of the visual accommodation system. These efforts, with additional

support from the National Eye Institute of the National Institutes of Health, allowed SRI International to invent and develop the Dual-Purkinje-Image (DPI) eyetracker. This system works by tracking a pair of reflections from the front surfaces of the eye using invisible infrared light which operates through a dichroic mirror. There is no requirement for a contact lens. Accuracy is as good as, if not better than, that provided by the contact lens method.

The Eye Research Institute of Boston has developed a laser coagulator system which can focus a laser beam onto the retina with no attachments to the patient's eye. In 1981, the laser coagulator and the DPI eyetracker were successfully merged into one system and tested as part of an effort with the NASA Ames Research Center. The objectives were to (1) configure the laser input system so that the eyetracker output signals might steer the beam and (2) merge the two instruments mechanically so that they

did not interfere with each other.

Initial trials with animals in 1983 successfully demonstrated the capability of the instrument. The point-of-contact with the laser beam on the patient's retina is not affected by the patient's own eye movements. Newly designed safety features now are being incorporated which will allow a high-power laser source to be used in retinal repair procedures with human patients.



Control of limbs is a special problem for a child with cerebral palsy. The child's movements are weak, poorly coordinated, and jerky due to poor muscular control. Walking can be helped, however, through the prescription of physical therapy for individual leg muscles.

In order to prescribe a specialized program of therapy, it is necessary to measure a child's precise walking pattern. In the past, the child was connected by means of a bundle of wires to a recorder and a display to measure specific muscle movements. It was found that young patients often were inhibited by the awkward tangle of trailing wires and the electrodes attached to the body. This made it difficult to obtain clear and consistent readings of their movement patterns.

An orthopedic researcher at the Children's Hospital at Stanford in Palo Alto, California, learned of the body sensors developed for the space program and contacted the NASA Ames Research Center for assistance. Ames

engineers, drawing on their experience with electronic systems used to monitor the movements of astronauts during space flight, developed a bio-telemetry system to measure the gait of cerebral palsy victims. The miniature transducers were affixed directly over the muscle groups being studied, with impulses then sent by wire to a small transmitter worn around the patient's waist. The transmitter relayed the signals to a receiver in another room where the data was recorded. While this was a significant improvement over earlier techniques, problems remained. The belt package containing the transmitter caused concern in the child and changed his gait. Also, the wire pickups and the signal mixing at the transmitter caused considerable electronic noise.

L-M Electronics, of Daly City, California, again working with the NASA Ames Research Center, recently developed a new gait analysis system with refinements which correct the earlier problems. This is a multi-chan-

nel transmission system with eight individual crystal-controlled transmitters, each operating on a different frequency. The belt package and all wires leading from sensors thus are removed. Each transmitter is positioned at the point of interest. In one application, each foot had a transmitter that sent information on four points of contact, showing exactly what part of the foot was touching the ground. At the same time three additional transmitters were affixed to each leg muscle group. These would transmit the electromyogram (muscle firing) of the particular muscle that was used in synchrony with the foot placement. A physical therapist then could determine the precise techniques required to help the child.

The new gait analysis system, commercially available through L-M Electronics, has been acquired by the Veterans Administration, a civilian hospital, and two universities with gait analysis centers for use in physical therapy programs.



Placement of leg transmitters in the advanced gait analysis system.

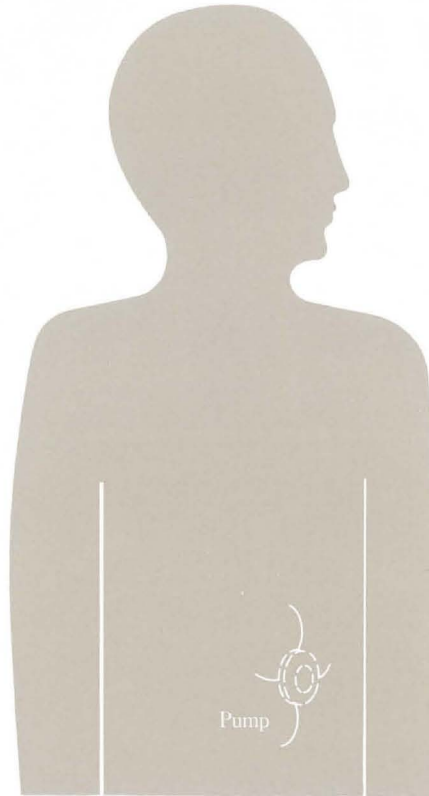
Technologies in the Process of Transfer

1	Implantable Biomedical Systems	26
2	Programmable Implantable Medication System (PIMS)	27
3	Automatic Implantable Defibrillator (AID-I and II)	28
4	Liquid Cooled Garments	29
5	Vascular Access Device	30
6	Prosthetic Urinary Sphincter	31
7	Ocular Screening System	32
8	Speech Autocuer	33
9	Hip Joint Biotelemetry	34
10	Versatile Portable Speech Prosthesis	35
11	Non-invasive Lung Diagnosis	36
12	Microspheres	37
13	Unistik	38
14	Computer-Enhanced Angiogram	39

Implantable Biomedical Systems

One of the most significant advances in modern medicine is the development of implantable systems to control a variety of heretofore intractable medical problems. The dramatic advances in this field come from a coherent program drawing on medical scientists and engineers, universities, industries and Federal agencies. The biomedical engineering issues have been enormous, with solutions coming in many instances through use of the expertise and technologies developed at NASA.

This field covers the spectrum from systems in everyday use to those existing today only as concepts. Most, however, represent technology in the process of transfer.



Implant Technology



Programmable
Computer Control



Internal Sensor
Technology

■ Rechargeable Pacemakers

■ Human Tissue Stimulator

■ Programmable Implantable
Medication System

■ Automatic Implantable
Defibrillator—II

■ Hydrocephalus Shunt

■ Sensor Actuated
Medication System

Programmable Implantable Medication System

The traditional administration of drugs for medical reasons is by mouth or by injection. In many instances, these procedures do not produce optimum results. There are a number of drugs which achieve desired effectiveness only when delivered to the bloodstream at a constant rate. A one-time dose, either orally or by injection, provides a high level of the drug in the blood immediately after administration, with a gradual decline thereafter. For many conditions, such as treatment of heart irregularities, neither the high initial level nor the subsequent low level is desirable. The peak-and-valley effect works against the purpose of the medication.

The history of implanted drug delivery systems can be traced to 1937 when implanted hormone preparations were tested with livestock. The development of programmable delivery systems, suitable for human application, is a recent event. While such a system will aid in management of many diseases, the thrust at this time is toward better control of diabetes. One million diabetics in the United States depend on daily insulin injections to help control blood sugar levels. Medical scientists

believe that more reliable control of these blood sugar levels would diminish the incidence of the many complications associated with diabetes. In addition, it would improve an individual's lifestyle by removing the requirement for 2 to 4 insulin injections daily.

A Programmable Implantable Medication System (PIMS) has been developed by the Applied Physics Laboratory, Johns Hopkins University, and the Technology Utilization Office, NASA Goddard Space Flight Center; Pacesetter Systems, Inc., Sylmar, California; and Parker-Hannifin/Bio-medical Products Division, Irvine, California.

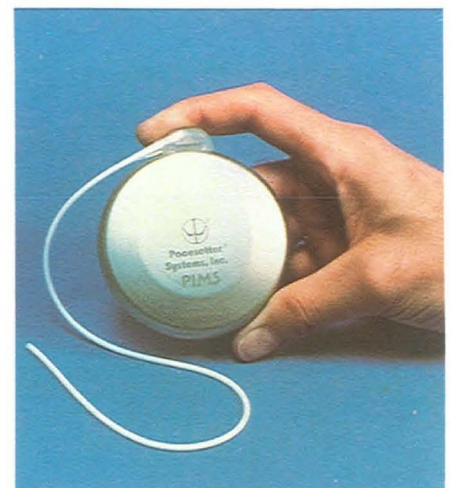
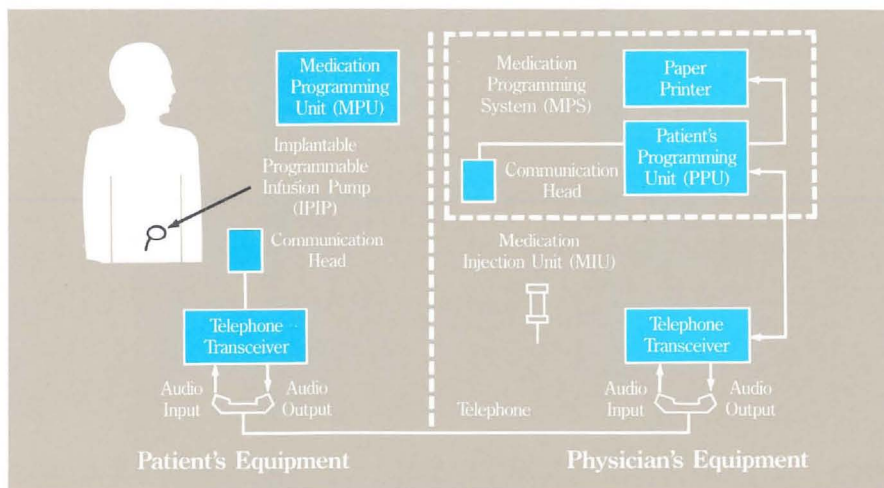
The implanted element in PIMS is the Implantable Programmable Infusion Pump (IPIP). An external unit programs the IPIP after implantation via command and telemetry systems. A physician can construct a basal medication delivery schedule which repeats within a period of 24 hours. In addition, up to six different supplementary schedules can be programmed to be delivered upon request of the patient.

The microminiaturized hybrid circuitry used for the pump system as well as the programming unit is based

on NASA technology. The command and telemetry systems draw on technology used with small astronomy satellites. Parker-Hannifin, the organization which developed the miniaturized fluid controls used for metering nutrients into the soil samples in the Mars Viking spacecraft, provided the miniaturized pump for PIMS. This pump is capable of metering medication in precise doses—about a millionth of a liter at a time.

Animal studies have been conducted to verify the system's efficacy in the treatment of diabetes. To date, four IPIPs have been implanted in diabetic dogs. Results demonstrate the ability of PIMS to normalize plasma glucose levels.

At the completion of clinical testing and acceptance for human use, Pacesetter Systems, Inc. and Parker-Hannifin plan to manufacture and market the Programmable Implantable Medication System.



Automatic Implantable Defibrillator

Over one million Americans suffer heart attacks each year. Approximately half of these survive the attack, but roughly 50,000 of this group die within one year, mostly from ventricular fibrillation. When it can be applied in time, electric shock defibrillation is generally successful in restoring a normal beat pattern to the heart. Unfortunately, most of those who die each year from a fibrillation episode are away from a hospital, where they could receive proper treatment.

The Automatic Implantable Defibrillator (AID) offers a solution to this problem by implanting within the bodies of persons at risk a sensing system to detect the onset of fibrillation or other potentially fatal arrhythmias and to automatically deliver a balanced electric pulse to restore the heart to a normal rhythm. Work for the development of AID-I began under the direction of Dr. M. Miroski of Baltimore's Sinai Hospital and the Johns Hopkins School of Medicine. AID devices manufactured by Intec Systems, Inc., have been implanted in 238 human patients at 20 medical centers. Of these 238 patients, 70 have had a total

of 205 spontaneous arrhythmic episodes in which normal heart rhythm was restored by the implanted AID device. The annual death rate for this series of patients was reduced to only 4.6 percent from typical rates of 30 to 66 percent.

Work is being conducted at this time toward an improved Automatic Implantable Defibrillator System (AID-II). This work is being conducted under contract from the Goddard Space Flight Center with the Applied Physics Laboratory, working in conjunction with INTEC of Pittsburgh, Pennsylvania.

Technology from the space program is being applied toward three objectives. The first is to redesign as feasible the current AID using principles and components whose capabilities and reliabilities have been validated by use in spacecraft.

The second objective is to develop an external recorder capable of monitoring and recording the patient's ECG at any time when the patient's heart goes into fibrillation. A spacecraft-type, low power, solid state digital memory could be used to obtain an 80

second recording of the first defibrillator episode in a particular time period. This would also provide a patient with an indication that a defibrillation shock was administered.

The third objective of AID-II is to greatly increase its capability. The improved AID will provide a demand pacer function to restore normal rhythm to an asystolic heart, an automatic test sequencer and low battery voltage detector, programmability allowing adjustment by the doctor, early warning of an impending defibrillation episode, and a four function internal event ECG recorder. The AID-II concept offers very sophisticated and advanced support for individuals suffering from heart problems.



Liquid Cooled Garments

The NASA Ames Research Center developed liquid cooled garments to provide more efficient and effective heat removal for astronauts wearing space suits. Water-perfused "panels" were designed which can be positioned over major muscle areas to remove excess body heat. The panels are constructed of two layers of urethane-coated nylon which is heat sealed to form integral channels to direct the flow of cooling water. The panels are connected to each other and sewn inside a close fitting garment which is then connected to a pumping/cooling unit by inlet/outlet tubing. This panel construction provides a close, comfortable fit to the body and promotes effective heat removal.

There are many medical applications for a system which provides partial or total body cooling or warming. The Ames system also is used in various medical research programs. These programs include studies of total body thermal control in cancer therapy and neonatal warming and cooling during surgery. Partitional body cooling has been effective in several areas: head cooling to reduce hair loss during chemotherapy, torso cooling of spinal cord injury patients during hot weather, torso cooling of patients who cannot perspire, and cooling of limbs of patients with a rare superheating problem.

The cooling vest illustrates further development of cooling garment technology. The construction of the vest is

unique in that it incorporates a third intermediate layer between the two outer urethane-coated nylon layers. This third layer is made of a synthetic material which is woven and heat sealed to form integral corrugated channels which are essentially noncompressible and thus insure water passage even when the garment is compressed, such as when leaning against the back of a seat or under heavy loads. The simple design and construction of this garment provides reduced manufacturing costs for medical applications.



Advanced procedures in medical technology which offer such dramatic hope for heart disease, kidney disease and other afflictions require access to the body. With some, electrical connections must be made. In other instances, the blood must be drawn temporarily from the body for treatment. In all cases, an invasive connector is required.

Any invasive system carries with it certain problems. If a simple puncture is used, there is post-treatment bleeding, tissue swelling, and the formation of bruised areas. If a permanent connector is implanted, there is a high risk of infection and rejection by the body. The challenge is to develop a permanently implanted connector with biocompatibility—one which can be used for a long period with no attendant complications.

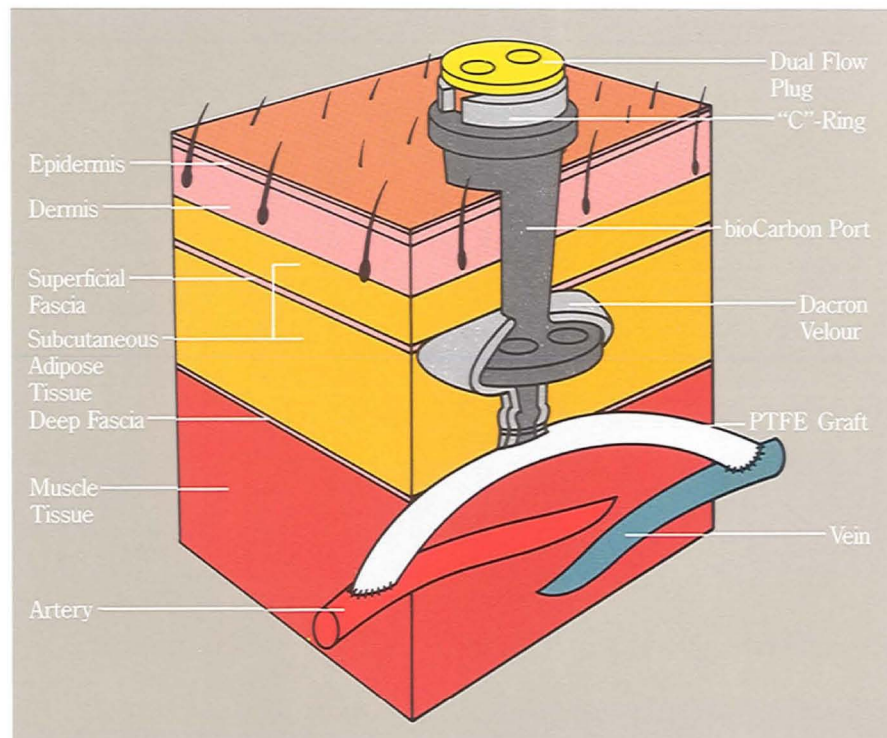
Pure carbon is one of the most biocompatible substances known. However, most forms are not strong enough for extended use. High

strength forms of carbon, designed initially for space capsule heat shields, were studied, under NASA support, at the Rancho Los Amigos Hospital in Downey, California. Vitreous carbon was found to meet the requirement for biocompatibility, to be light weight and appropriate strength.

The preparation of percutaneous (through the skin) connectors is as important as the selection of materials. The NASA Lewis Research Center has been working with Applied Medical Technology, Inc., to use ion-beam sputtering techniques developed in the NASA Electron Propulsion Program to texture percutaneous connectors with a regular array of micropillars (small raised points). These inhibit tissue downgrowth and subsequent rejection of the connector.

American Bentley, a subsidiary of American Hospital Supply Corporation, now offers a Vascular Access System using a vitreous carbon implant which is virtually non-reactive

with tissue, blood or chemicals. The implant does not interfere with routine patient activities and provides an air- and moisture-seal between treatments. Patients requiring chronic dialysis procedures are afforded considerable convenience since treatment may be given either at home or at a medical facility.



Positioning of bioCarbon® vascular access implant.



Micropillar array.

Prosthetic Urinary Sphincter

Urinary incontinence drastically affects a sufferer's ability to lead a normal life. In addition to the inconvenience, external collection devices leave a constant residual urine in the urethra and bladder, where it serves as a medium to support bacterial growth. In paraplegics, who are permanently incontinent, kidney failure from bladder infections is the most frequent cause of death.

Aerospace technology has been applied to the development of a simple, reliable prosthetic urinary sphincter control system to enable urinary incontinent patients to achieve external voluntary control of bladder function. This program started when Dr. William G. Montgomery, a researcher treating paraplegics at Bowman Gray School of Medicine at Wake Forest University, saw the need for a simple but reliable valve device that could be surgically implanted and easily controlled by the patient. Dr. Montgomery contacted NASA's Technology Ap-

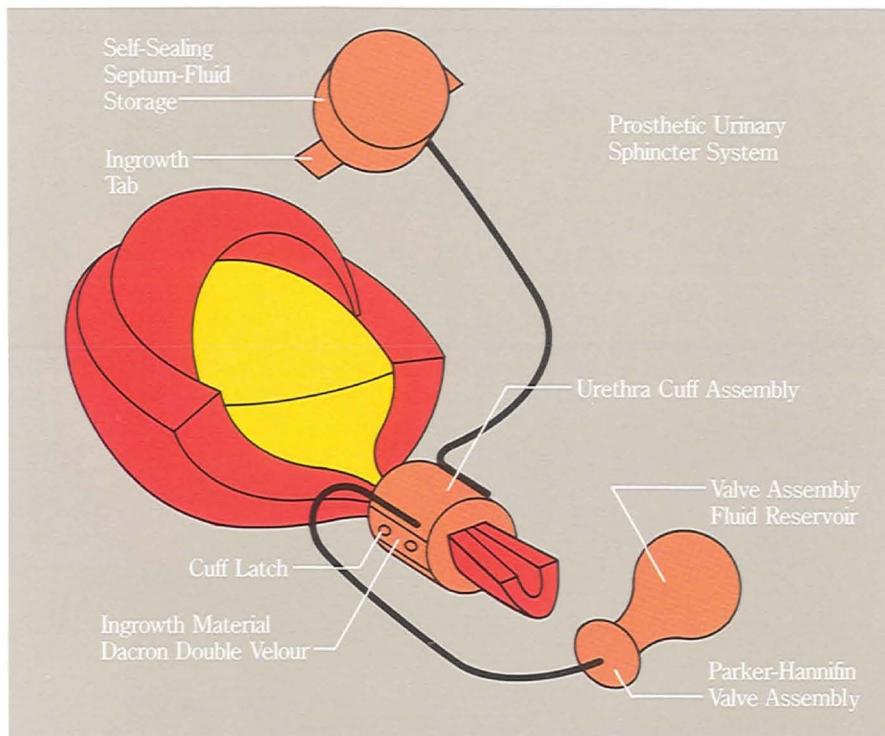
plications Team at the Research Triangle Institute in North Carolina. A project then was started through the Marshall Space Flight Center with a key feature being the adaptation of the low pressure, zero leakage, high reliability valves used on the Viking Spacecraft.

The five year development program, which was recently completed with successful animal trials, was conducted under the direction of a research team at Rochester General Hospital. Parker-Hannifin Corporation manufactures the valve assemblies based on aerospace technology. Medical Engineering Corporation, of Racine, Wisconsin, plans to market the device following government approval and clinical trials.

The sphincter system, an implant device designed for both male and female patients, contains a two-chamber inflatable, occlusive cuff placed around the urethra, a self-sealing storage system, a check valve mechanism, and a valve fluid reservoir. The sphinc-

ter system is implanted so that the valve/bulb assembly is accessible by manual pressure through the skin. The cuff applies pressure to occlude the urethra and maintain continence. The pressure can be released for voiding, then restored by manual manipulation of the valve.

Clinical trials of the prosthetic urinary sphincter are scheduled to begin in early 1985. When commercially available, this system will offer two important advantages over earlier devices. First, its simplicity promises to reduce the surgical complexity of the implantation procedure. Second, the high rate of device malfunction with existing devices, often due to valve failure, should be dramatically improved.



Implantable Prosthetic Urinary Sphincter System.

Ocular Screening System

Early detection and care of visual abnormalities in school children is most important. An economical, highly reliable ocular screening system has been developed to detect eye problems in children through a photometric analysis of retinal reflexes.

The Generated Retinal Reflex Image System photorefractor is capable of testing the human visual system for refractive error and defects in the retina or interior chamber and for obstructions in the cornea. It also can detect ocular alignment problems.

Key units in the ocular screening system consist of a 35mm camera body, using color film, a telephoto lens and an electronic flash. This system measures the retinal reflex by means of a direct photograph of a subject's eyes, taken in a dark room to facilitate pupil dilation. The color retinal reflex images then are analyzed by experts to determine eye problems.

The project started when an ophthalmologist in Huntsville, Alabama, contacted the Marshall Space Flight Center Technology Utilization Office to request a technical evaluation and as-

sistance in developing a photorefractor device. The resulting system, developed with the assistance of a small business, Electro Optical Instruments, does safe, low-cost screening for amblyopia (dimness of sight) and other eye diseases, especially for children too young to communicate. Independent tests conducted by the Smith-Kettlewell Eye Research Foundation in San Francisco graded the accuracy of a prototype system at 88 percent.

The system is capable of detecting eye anomalies such as hyperopia, myopia, astigmatism, strabismus, retinal pigmentation pattern and lens obstructions. It was used initially in a mass screening of students at the Alabama School for the Deaf and subsequently by a Huntsville Lions Club in a screening of 1,835 kindergarten and first grade students. Five hundred and seven were found to have abnormal retinal reflexes. University of Alabama researchers also are testing a select group of 441 students with learning disabilities to determine possible relationships between these problems and eye abnormalities. Of these students,

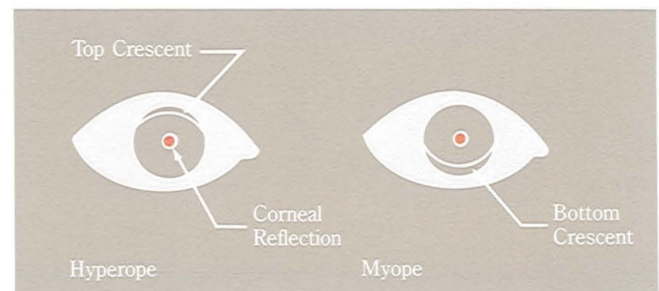
255 were found to have abnormal retinal reflexes.

The ocular screening system is an effective measurement device which is economical, portable, and non-invasive. It is a promising technique for large-scale screening of children to detect visual problems at an early stage. The system was expected to be commercially available in late 1984 through Electro-Optics Consultants, Inc., a small business firm in Alabama.



Sex	Male	Rt	Lt
VA	Uncorrected	20/200	20/200

Photograph made with Generated Retinal Reflex Image System.



Visual anomaly patterns.

The successful development of a wearable, real-time speech perception aid has the potential to improve the economic status and quality of life for the 1.8 million deaf people in the United States. Research has been completed which demonstrates that deaf people can perceive speech accurately through a prosthesis based on Cued Speech. Called the Autocuer, the speech analyzing prosthesis presents automatically derived visual cues in real-time to a wearable eyeglass display which, in combination with lip reading, enables accurate speech perception by deaf people.

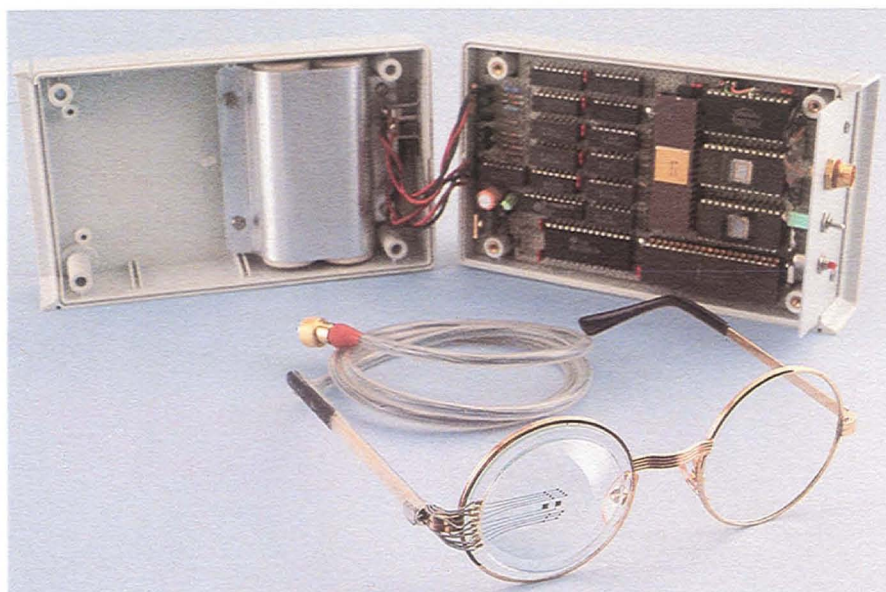
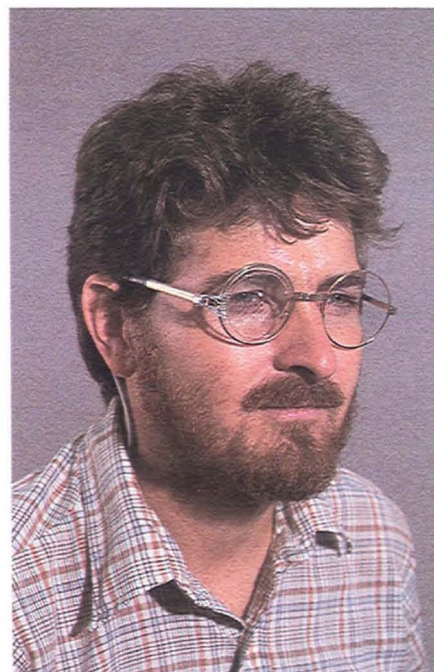
The Autocuer project is a four-way collaboration between Research Triangle Institute (speech analysis, hardware and software design), Gallaudet College (laboratory training and testing, field test), NASA Goddard Space Flight Center (project coordination, technical consultation), and Telesensory Systems, Inc. (fabrication of field test units, commercialization). NASA and the Veterans Administration provided support for the work.

Capitalizing on the pioneering ef-

forts of NASA in developing complementary metal oxide silicon (CMOS) low-power electronics for space missions, work began in 1979 to develop a low-power, wearable microcomputer to adequately analyze connected speech for successful automated cuing.

The last two of the large scale integrated circuits needed by the Autocuer for producing accurate real-time speech analysis in a wearable package have now been incorporated into the design and are being verified to meet project requirements. When this step is completed, the design will be released to Telesensory Systems, Inc., for fabrication of 24 units for use in the field test.

Scheduled to begin in 1985 and last one year in duration, the field test will include deaf adults from 20 to 60 years of age and prelingually deaf children, all of whom have a good knowledge of spoken English. A commercially available Autocuer will follow when the field test demonstrates that the unit works in the real-world speech environment.



Over 100,000 total hip replacement operations are performed each year in the United States. Unfortunately, a number of these do not have lasting success. X-ray evidence of femoral component loosening in excess of 20 percent has been noted in reports from the Mayo Clinic in 1978 and from UCLA in 1979. Failure reports indicate that prosthetic loosening may be found in up to 24 percent of older patients in as little as seven years, and in up to 54 percent after only five years in patients under 30. Mechanical complications of implant breakage, cement fracture, skeletal loosening, and component wear are directly related to the transmission of force across the joint. With younger patients who will have greater performance expectations from their replacement joint, we may expect increasing rates of failure due to the increased transmission of force across the joint.

The estimation of joint forces involves calculations based upon mathematical idealizations of joint geometries and material properties. The accuracy of such calculations is not known since dynamic effects due to the musculature can only be estimated.

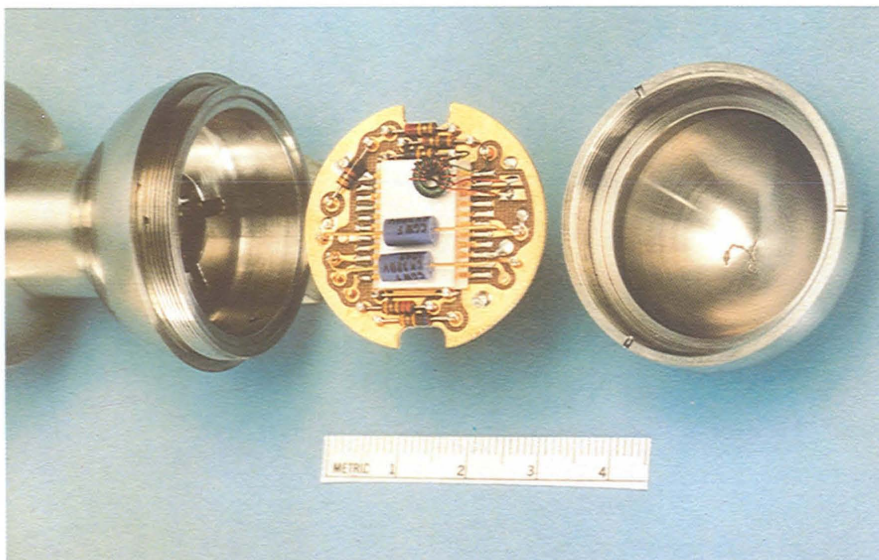
The NASA Jet Propulsion Laboratory, in cooperation with the Biomechanics Section of the Division of Orthopedic Surgery at UCLA, in 1977 began the development of a prototype biotelemetry package to be sealed within a total hip replacement implant. This system will give *in vivo* data as a patient goes about his or her daily activities, thereby providing engineering data not previously available for the improvement of hip joint design.

The experience of JPL with miniaturized remotely controlled space telemetry systems has resulted in a design overcoming many of the difficulties previously encountered in powering implants. Rather than using batteries or wires through the skin, most of which are at best awkward, the JPL design relies on induced power. With this technique, the patient needs only to wear a cuff, much like that used to take blood pressure readings, around his thigh. Power is transmitted from coils of wire in the cuff to an antenna built into the hip joint implant. Data from strain gauge sensors within the system are read out through the same induction system. Thus data can be collected over months or years, with no discomfort to the patient. At

all times, the implant will function in a normal manner.

Data from the completed system will provide the first *in vivo* loading information from a total hip replacement. Even if only one patient implantation is achieved, the information will be invaluable. Direct measurement of hip force with walking aids, casts, and modified gait patterns will give a relative measure of the effectiveness of these techniques. Validation of mathematical models will be possible. These data will be of value in understanding the mechanical forces responsible for prosthetic loosening and fracture and will also show wear patterns on internal components such as the acetabular cup.

Work is proceeding at this time on engineering models for actual implant. This effort, funded by the Veterans Administration, pending Government approval for use in human subjects, will result in data describing forces on human hip joints by 1986. This information will be invaluable for the improvement of future hip joint systems.



Versatile Portable Speech Prosthesis (VPSP)

The number of people in the United States with speech impairment is estimated at about two million, or about one percent of the total population. As many as one-half of these, up to one million, are believed to have serious or disabling speech impairment which requires the use of some type of communication aid, or speech prosthesis. While there are a number of communication aids with visual and printed outputs, a speech aid provides faster and more efficient communication, easier group or classroom participation, telephone conversation, the ability to communicate with children who cannot read, a way to interrupt or initiate communication, and the psychological benefit of being able to speak.

The Versatile Portable Speech Prosthesis (VPSP) is a synthetic speech output communication aid for non-speaking people designed to be placed on a wheelchair and powered from a wheelchair battery. The versatility of the VPSP allows it to accommodate a variety of input devices including single switch, multiple switch, joy stick, or other keyboard controls which physically limited people have the ability to use. It speaks with a synthetic voice for people unable to speak with

their own voice.

The VPSP employs a microcomputer with a phoneme speech synthesizer and a specially designed television screen. The user composes speech messages by accessing desired words and phrases from a "starter vocabulary" in the microcomputer's memory as they are displayed on the matrix board of the television screen. After selecting a message, it is entered by manipulating a control switch which illuminates the words or phrases one wishes to say. The microprocessor then activates the speech synthesizer device which speaks the message aloud. The users also can develop their own messages and store them in the computer for later use. In clinical trials, all users felt that the VPSP was a great help to them. The message construction time varied from one to three words per minute with the one-switch version to ten words per minute with a keyboard, using single-finger typing.

The VPSP is the first communication aid to rely on synthesized speech. It was developed by the Rehabilitation Engineering Center, Children's Hospital at Stanford, Palo Alto, California. The speech synthesis procedures

were based on extensive psycholinguistic human factors research conducted by the Man-Machine Integration Branch of the NASA Ames Research Center. This research initially was directed at applying synthesized speech in airplane cockpits as an effective means of warning pilots of dangerous situations.

The Versatile Portable Speech Prosthesis has been successfully tested as a proof-of-concept system and is available for commercial development. Although designed as a wheelchair-mounted system, it can be used in other situations to aid persons not capable of speaking.



Non-Invasive Lung Diagnosis

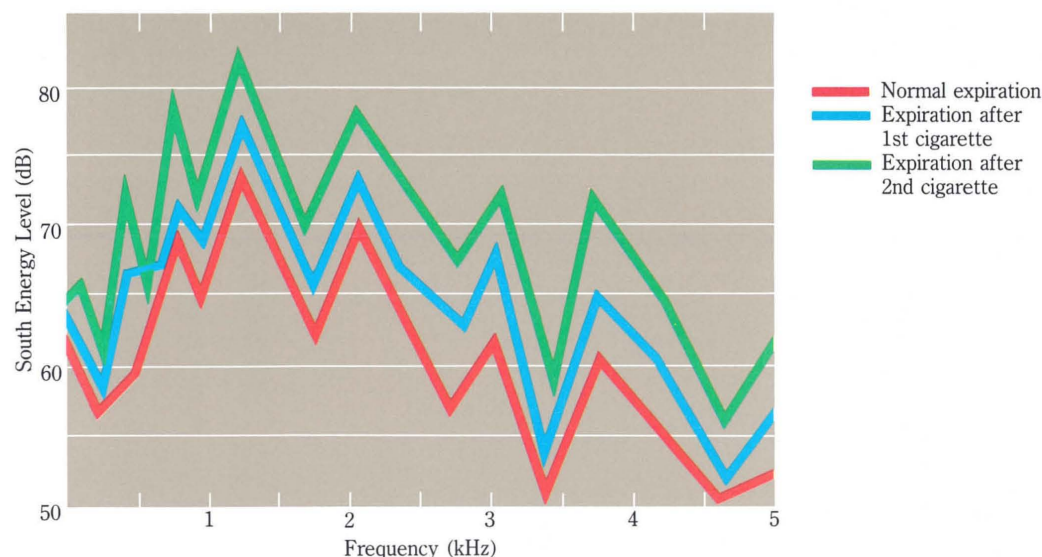
The prognosis for many forms of pulmonary disease is improved with early detection, accurate diagnosis, and the immediate initiation of an appropriate program of therapy. Disabling pulmonary illnesses may develop as a result of occupational and environmental factors, pulmonary vascular pathology, cystic fibrosis, asthma, or cigarette smoking. Management of these illnesses requires new methods to insure early detection.

Research in aeroacoustics conducted at NASA's Langley Research

Center has provided a basis for a theory of the origin of human respiratory sounds derived from the motion of vortices in the human lung. The nature of a given pulmonary illness should cause a distinct change in a pattern of air flow through different regions within the lung. The developmental work in pulmonary acoustics and the validation of this theory using lung models has been accomplished by the Theoretical Acoustics Branch, NASA Langley Research Center, and the Medical College of Virginia. This work includes

the development of a technique of sufficient sensitivity to record and analyze human respiratory sounds as these sounds are changed by minimal lung dysfunction.

B&K Instruments, Inc., of Cleveland, Ohio, is supporting this project with engineering consultation and equipment, believing it has potential commercial value as a diagnostic system. It predicts a market for the system in employee industrial check-up centers as well as in hospitals.



All living tissue is made up of individual building blocks called cells. In medical research, it is important to be able to identify, examine or separate different types of cells. But the techniques for doing so have always been time consuming and inexact. Faster and more versatile techniques would not only benefit research, but would also have potential application in the diagnosis and treatment of diseases. Scientists at NASA's Jet Propulsion Laboratory have developed a novel cell-labeling technique for a variety of such applications.

The technique is based on the preparation of microspheres, tiny bubbles made from synthetic polymers, that can be chemically bonded to antibodies, special molecules produced by the body's immune system. In turn, the antibodies are able to seek out, recognize, and attach themselves to molecules called antigens found on the surface of specific cells. In the process, the antibody brings the microsphere along with it. Because each antibody will attach only to a specific type of antigen, the microsphere can be directed to a certain kind of cell by

bonding it to the right type of antibody.

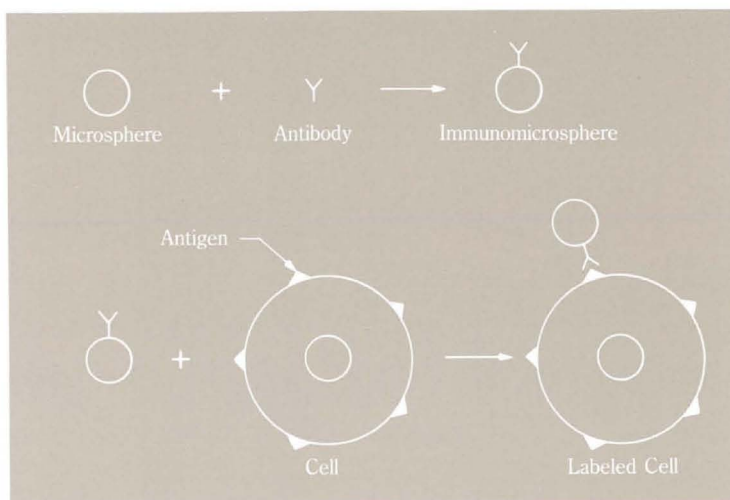
The most exciting part of this process from a medical standpoint is that microspheres can be filled with a variety of substances which are injected into the cell. This produces the cell "labeling" effect. Depending on the substance used, the cell can be labeled in different ways for different purposes. For example, if the microspheres are filled with a radioactive substance, specific cells can be identified and counted by means of the radioactivity they absorb. Similarly, labeling with a fluorescent substance will permit both identification and separation of the labeled cells, using a special cell-sorting instrument. Imparting a magnetic field to the microspheres provides another way to separate labeled cells from non-labeled cells.

For treating disease, the microspheres can be filled with a drug that can alter or destroy the specific cell to which a microsphere attaches itself. Thus, the microsphere-antibody combination (called an immunomicrosphere) becomes a "smart bullet" targeted at the diseased cell. This tech-

nique has already been tested successfully in the laboratory for treating cancer cells.

In a 1983 clinical procedure in London, physicians removed ten percent of the bone marrow of a patient suffering from neuroblastoma. The removed bone marrow was treated with magnetic immunomicrospheres, and a magnetic field was applied to separate the magnetic, malignant cells from the non-magnetic, healthy cells. The healthy bone marrow was then replaced in the patient. Since that time, about 20 young people with neuroblastoma have been treated using this procedure. Significant improvement has been noted in most of the patients.

Use of microspheres has great medical potential. With further development, the work begun by JPL may lead to cancer therapies that are more effective than existing radiation and chemotherapy, for example, and lack their debilitating side-effects.



Direct immunological labeling of living cells with microspheres covalently coupled to antibodies.

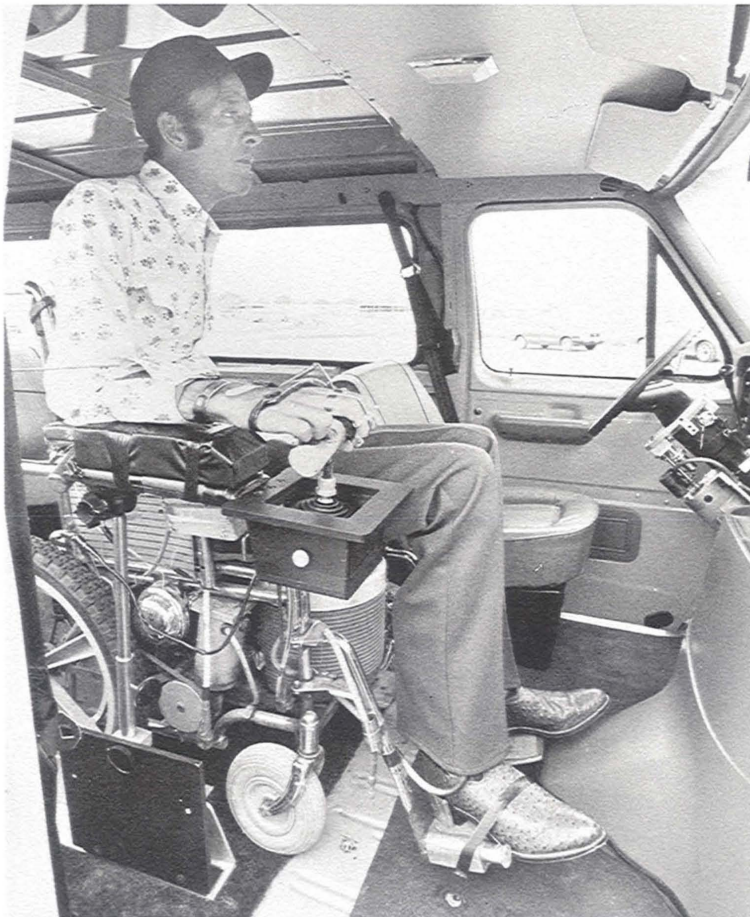
Driving an automobile is a complex perceptual-motor activity requiring use of all four extremities. For a handicapped person, this activity is difficult, if not impossible. In most instances, independent transportation is not achievable for the severely handicapped and represents a real barrier to their leading productive lives.

The National Aeronautics and Space Administration, through its Technology Utilization Office and working in conjunction with the Veterans Administration, is managing a program to use Lunar Rover Vehicle technology from the Apollo Program to aid in the development of a control system which will enable severely handicapped people to drive a conventional motor vehicle. During the Apollo missions in the

1970s, astronauts drove the Lunar Rover using one hand to accelerate, brake, and steer as they explored the surface of the moon. The UNISTIK uses a two-axis joystick to control electric motors which position the controls of a standard motor vehicle. Moving the stick forward depresses the accelerator pedal, rearward depresses the brake pedal, while left or right movements turn the steering wheel in the appropriate direction. The system uses a "fly-by-wire" type of control used in spacecraft and in certain high speed aircraft rather than the conventional direct coupling of control to actuator.

The design of the driver's control system is based on a human factors analysis of the control capabilities and

limitations of quadriplegics who have suffered lesions of the spinal cord at the fifth cervical vertebrae. Inputs to the design study were made by a quadriplegic and several patients at the Craig Rehabilitation Hospital in Inglewood, Colorado. Johnson Engineering Corporation (formerly Nelson and Johnson Engineering, Inc.), the firm which has worked with NASA and the VA to develop this system has tested a prototype UNISTIK in a 1981 Ford Van. The Van has been successfully driven by several quadriplegics. This is a major step forward in opening the normal world to the severely handicapped.



UNISTIK being used for control of the Van.

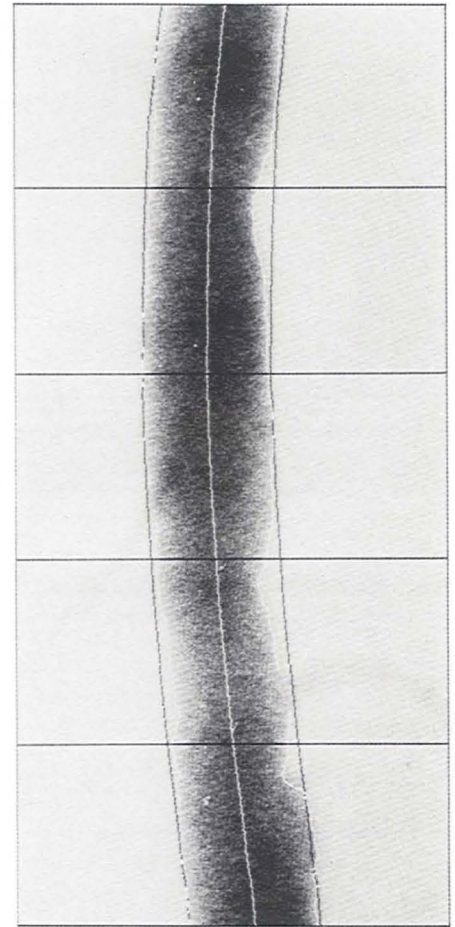
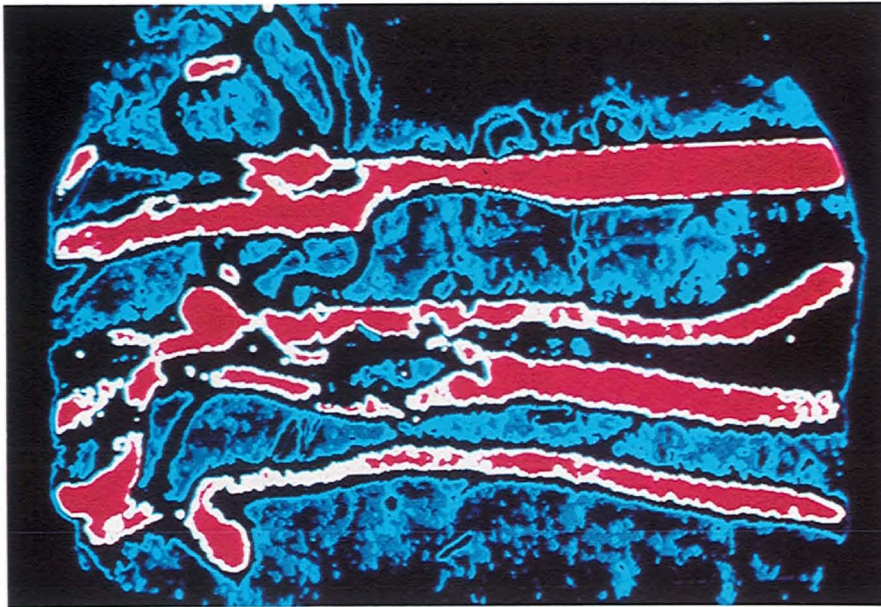
Computer-Enhanced Angiography

The value of this technique lies in its capacity for making long-term comparisons and in its accuracy. In clinical studies, such as those at USC, it can measure small changes in lesions identified in progressive angiograms taken over intervals of time. This computer-aided method also shows a precision error of only about four percent, as compared to about 25 percent for the visual inspection method.

Because angiograms involve an invasive procedure with some risk to the patient and the use of ionizing radiation, the computer-aided, image-analysis technique developed at JPL must compete with presently developing non-invasive techniques, such as nuclear magnetic resonance and ultrasound, which are apparently risk-free

and which use non-ionizing radiation. However, there are types of examinations that cannot be performed as well with ultrasound (for example) as with angiography. In addition, this technique offers much finer image resolution than even the improved ultrasound instrument developed at JPL. Perhaps the most promising approach, however, will be to use these same basic computer-image analysis procedures in conjunction with the JPL ultrasound device.

The technology described here is being evaluated through continuing clinical trials. Through extensive publication of the results achieved thus far, computer-enhanced angiography is expected to come into increasingly wider use.



Computer-determined angiogram of a femoral artery showing the edges of the arterial lumen (outline of dark area). Outer vertical lines estimate the outline of the normal (pre-diseased) arterial lumen.

Technologies Planned for the Future

1	Hydrocephalus Shunt	42
2	Sensor Actuated Medication System (SAMS)	43
3	System for the Measurement and Control of Hypertension (SYMCOH)	44
4	Corneal Topography	45
5	Nuclear Magnetic Resonance	46
6	Self-Injurious Behavior Inhibiting System (SIBIS)	48
7	Helicopter Medevac	49
8	Medical Measurement with Ultrasonics	50
9	Functional Electrical Stimulation	52

Hydrocephalus Shunt

Hydrocephalus is an excessive accumulation of fluid within the natural cavities of the brain. It is a condition in which the cerebral ventricles enlarge abnormally when the pressure of the cerebrospinal fluid rises. This is a result of some impairment of the normal circulation or reabsorption of the cerebrospinal fluid. In children, approximately 8,000 cases occur each year as a result of a cleft spine birth defect. There may be as many as another 3,000 cases per year in which the cause is unknown but may be associated with congenital neural tube defects, trauma, infection and tumors.

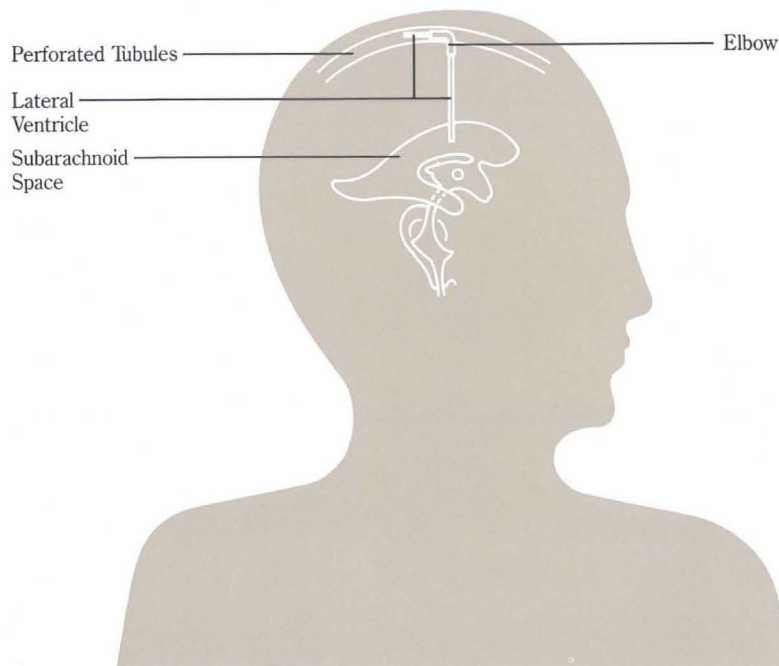
Treatment of hydrocephalus consists of the surgical insertion of a device to divert cerebrospinal fluid from the brain to another part of the body. While these drainage devices, called hydrocephalus shunts, have reduced mortality and other consequences associated with this condition, there are

a number of problems. An estimated 50 percent of hydrocephalus patients require at least one reoperation to replace or repair a malfunctioning shunt. Obstruction of either the ventricular or distal catheter is the major cause of shunt failure. The obstruction itself results from an accumulation of body tissue.

In 1981, NASA asked the Biomedical Applications Team of the Research Triangle Institute to determine if NASA technology could be successfully applied to the development of an improved hydrocephalus shunt. It was determined that technology developed in NASA's Ion Propulsion Engine Program might be used to perforate small-diameter catheters. A multi-ended inlet catheter, with hundreds of tiny inlets formed by ion-etching techniques, could minimize the blockage problem and reduce the incidence of shunt failure. The small holes would

inhibit tissue ingrowth and the multiplicity of holes would reduce the possibility of blockage.

A team consisting of scientists from the Ion Beam Applications Section, NASA Lewis Research Center; the Jet Propulsion Laboratory; the University of California at Irvine; and the Pudenz-Schulte Medical Research Corporation are working on the improvement program. Pudenz-Schulte is developing an animal model for evaluation of the Lewis prototype shunts and will conduct bench tests for shunt flow studies. At this time, the JPL team has successfully formed 15-micron holes in a teflon shunt, an encouraging step toward a successful new design.



Sensor Actuated Medication Systems (SAMS)

Hypertension, or high blood pressure, is a significant problem for the American workforce. In the civilian, non-institutional population between 25 and 74 years of age, there are over 16 million people classified as having definite hypertension. These individuals, representing 14 percent of the workforce, are at serious risk for heart attack and other diseases. In 1980, the deaths of over 32,000 Americans were attributed either to hypertension or hypertensive heart disease. In addition to these deaths, many more Americans developed chronic heart conditions, suffered strokes or developed kidney disease. Hypertension is a disease of great economic and social consequence for this nation.

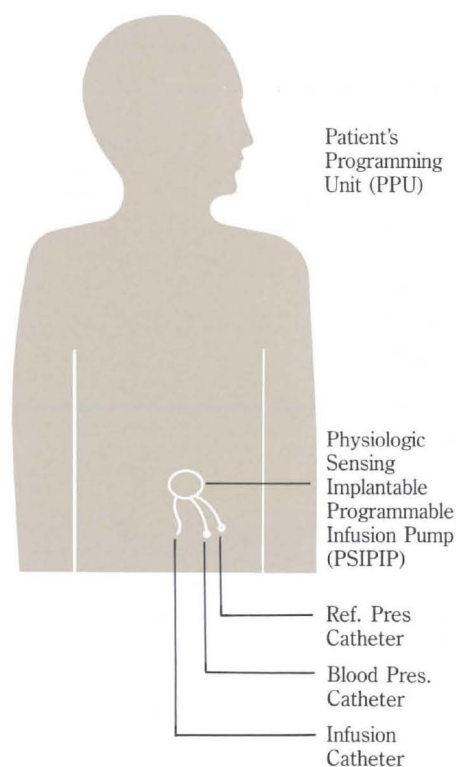
The National Heart, Lung, and Blood Institute, in a five-year program, found that death rates from hypertension could be reduced by 17 percent through a continuous and in-

tensive drug treatment program. Clinical experience, however, shows that it is difficult to maintain such a program in the normal workforce. Since hypertension in itself has no symptoms, most individuals have considerable difficulty in maintaining a regular medication schedule. Since they feel fine, what is the urgency in taking the medicine?

In an attempt to improve the control of hypertension through the continuous administration of medical agents, the Technology Utilization Program of the NASA Goddard Space Flight Center is supporting an effort to develop an implantable device for the treatment of hypertension. The Applied Physics Laboratory of the Johns Hopkins University is serving as project leader. The implantable device releases antihypertensive medication in accordance with signals received from a blood pressure sensing component.

With this system, the medication is continuously available and is administered in direct response to the needs of the body. This represents closed-loop control of hypertension through a sensor actuated microprocessor controlled medication infusion system.

In order to achieve the highest reliability, the SAMS development effort is using spacecraft-type microminiaturized hybrid circuitry and programming technology used on the Small Astronomy Satellite and other spacecraft. The program schedule calls for clinical trials to be completed within the next five years. The resulting system will do much to alleviate a major medical problem in America.



Implanted portion of SAMS system.

System for the Measurement and Control of Hypertension (SYMCOH)

The optimum procedure for controlling hypertension would be one which continuously monitors the blood pressure level and which can correct undesirable increases without the use of medication. Work conducted with NASA support indicates such a system may be feasible using the technology now being developed. The system concept is based on use of biofeedback procedures.

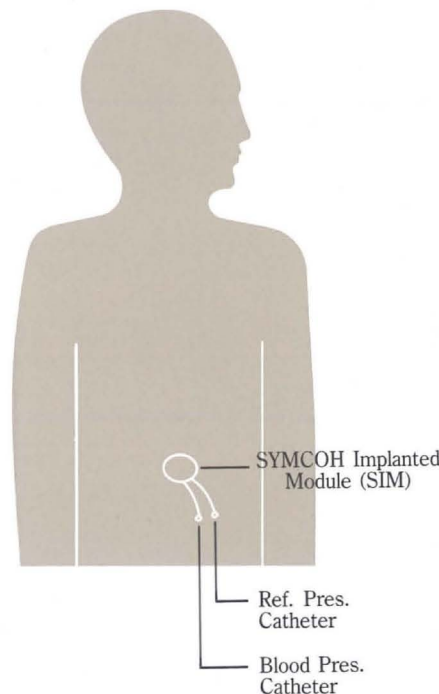
Biofeedback is defined as a process in which a person learns to influence or control physiological responses not normally under voluntary control. It is a type of self-regulation in which one learns to control activity normally mediated by the autonomic nervous system. The physiological responses most frequently used in biofeedback are heart rate, skin temperature, blood pressure, and peripheral blood flow. Hypertension appears to be an appropriate candidate for biofeedback.

The implantable system developed for administration of medication for hypertension control (Sensor Actuated Medication System [SAMS]) can be modified, in principle, to accomplish the same control through a biofeedback process. The System for the Measurement and Control of Hypertension (SYMCOH) includes an implanted module for sensing and recording blood pressure which provides an alarm signal if programmed levels are exceeded. This signal serves as the basis for biofeedback control of blood pressure. The biofeedback can be by subcutaneous electrical stimulation or by an audiotone whose frequency or pulse rate is proportional to blood pressure. This signal, which indicates both the occurrence and magnitude of a blood pressure increase, triggers the biofeedback response which in turn serves to reduce blood pressure.

The SYMCOH development pro-

gram will proceed in much the same manner as SAMS. The Goddard Space Flight Center will provide overall management guidance, with the Applied Physics Laboratory of the Johns Hopkins University performing the systems engineering application and development. The first evaluations of the SYMCOH system will be conducted at the Johns Hopkins Hospital. As with SAMS, clinical trials should be completed within the next five years. These trials will validate the operation of the implanted system and its controlling software. Additionally, they will allow the development of efficient techniques for teaching an individual the biofeedback skills necessary for this system to be successful.

Implanted portion of SYMCOH system.



Aerospace technology used to measure precisely the mirror surface of the space telescope is being applied to the development of an instrument that will accurately map the cornea. This instrument, called the Corneal Optical Topographical Scan System (COTSS), uses a laser beam to scan the eye to obtain information required to determine the precise shape of the cornea.

New surgical techniques for the treatment of human eye cornea disorders depend on accurate measurements of the shape of the outer surface of the cornea. An example is radial keratotomy in which eight to sixteen radial cuts are made in the outer layer of the cornea to cause the surface to flatten and reduce myopia. A very accurate mapping of the cornea is needed to establish the pattern of the cuts and to determine if the cornea is healing properly.

Another application is in cornea

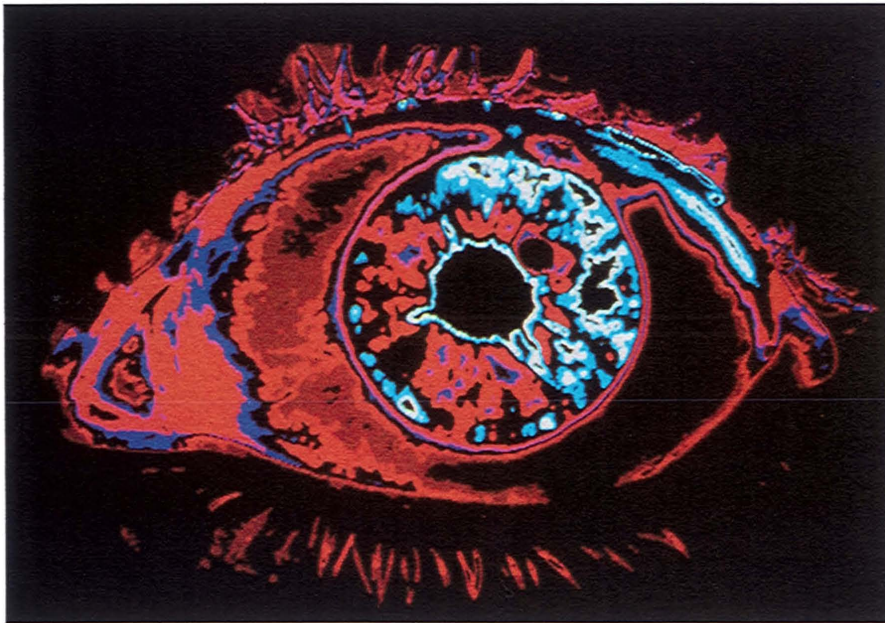
transplants, where the surgeon needs to have quick measures to determine if the sutures are uniformly stretching the new cornea. Damage from trauma such as cuts, burns, and punctures also requires quick diagnosis and accurate measurements of the extent of the damage.

The advent of faster and more accurate measurement techniques will even improve the fitting of contact lenses. Instruments now in use by ophthalmic surgeons do not provide the required accuracy or the necessary high speed, real-time rate of data collection.

Engineers at the NASA Marshall Space Flight Center developed an initial prototype of the Corneal Optical Topographical Scan System. As the laser beam on this instrument scans the cornea, radiant energy that the eye reflects from the laser beam is measured and processed in a special purpose computer. Within a few sec-

onds after the eye is scanned, a detailed topographical representation of the cornea is displayed on a color television monitor. This can be used immediately by the physician or, if he requires quantitative data for use in a lens prescription, the data stored in the special purpose computer can be analyzed and the results printed in hard copy.

Electro-Optics Consultants, Inc., a small business firm in Huntsville, Alabama, is under contract to the Technology Utilization Office of the Marshall Space Flight Center to construct a breadboard instrument for evaluating problems and demonstrating the concept. Following this, this company will repackage the system into a prototype that can serve as a basis for mass production.



Nuclear Magnetic Resonance (NMR) Imagery

The traditional means of examining internal body systems has been through use of X-ray imagery based on the differential absorption of X-rays by body systems of different density. Routine X-ray images, however, do not discriminate well among overlapping structures. Computerized tomography (CT scanning), in which a number of images are reconstructed mathematically to yield cross-sectional views of selected body regions, provides greatly improved information. Although the information is very useful, scanning images still do not provide information concerning the functional or physiological state of internal organs, particularly if pathological lesions exist which have X-ray absorption properties similar to surrounding tissue. Also, there is a measure of risk in using extensive X-ray procedures.

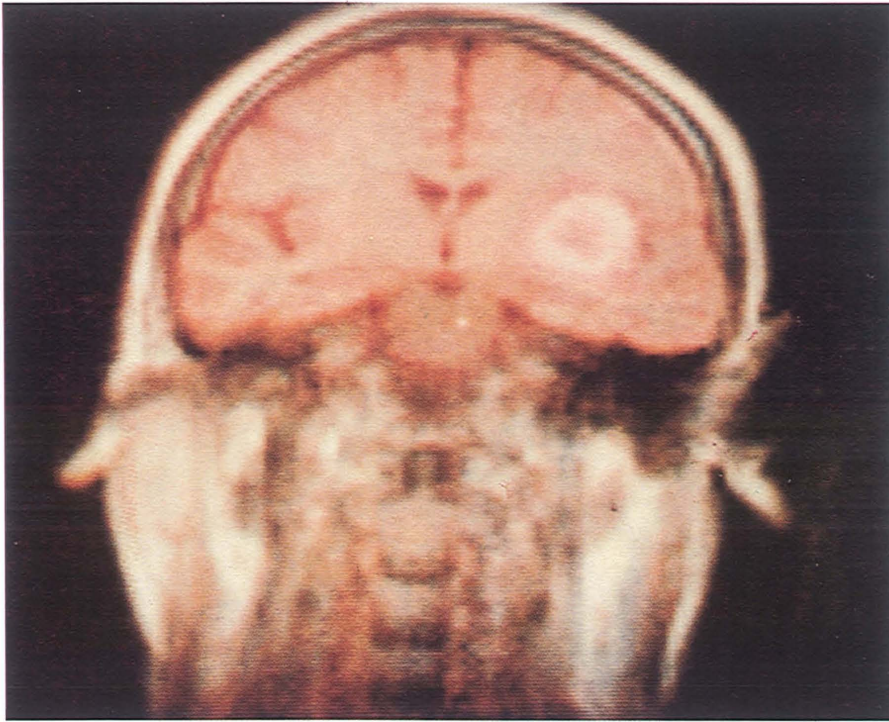
Nuclear magnetic resonance (NMR) imaging is a new technique for obtaining cross-sectional pictures within the body without use of ionizing radiation. NMR procedures are based on findings

in the 1920's that many atomic nuclei have an inherent property of rotation which, since nuclei are electrically charged, generates a small magnetic field. Nuclei with an odd number of nucleons (protons or neutrons) produce this magnetic effect. Hydrogen nuclei are excellent for these purposes, a fortuitous event for medicine, since hydrogen nuclei predominate within the human body.

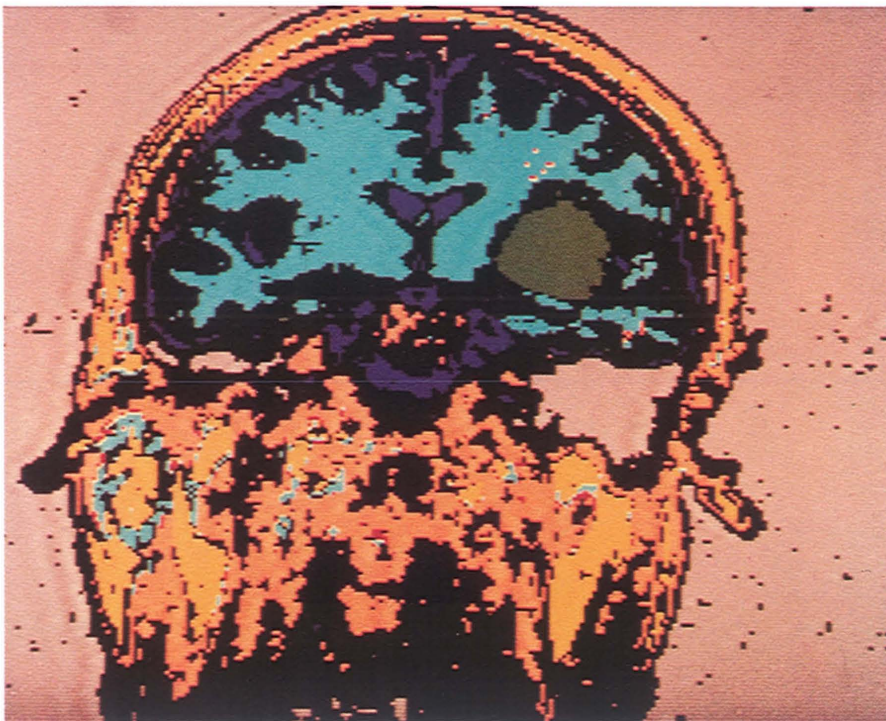
In nuclear magnetic resonance, a magnetic field is imposed on a sample in order to orient the nuclei in a direction parallel to the applied magnetic field. The composite spin vector is then tipped (processed) through the application of selected radio-frequency power. The nuclei reveal their location by emitting a signal of precise frequency for a brief period.

Scientists at the NASA Kennedy Space Center and the University of Florida are applying NASA multi-spectral image processing technology to analyze NMR medical data. NMR imagery includes sets of data for proton

density and relaxation times (T_1 and T_2) that are in registration for multiple sections through an organ or body region of interest. This is analogous to satellite images which include data sets based on measures of visible light, near infrared, and far infrared energy. Advanced image processing systems for the analysis of satellite data are being adapted for purposes of combining the different data sets in NMR imagery to obtain a single color picture. Results indicate that NMR imaging may be especially useful in identifying malignancies and degenerative disease of various kinds. The soft-tissue contrast is inherently superior to that of X-ray techniques. NMR is a new medical diagnostic tool which has great potential for solving medical problems having no current solution.



The return of nuclei to the original orientation also is characterized by two principal relaxation times T_1 and T_2 . These are the measures used in image production.



Self-Injurious Behavior Inhibiting System (SIBIS)

Children diagnosed as severely retarded, autistic, or schizophrenic frequently show a dramatic form of psychopathology termed self-injurious behavior (SIB). Eight to fourteen percent of retarded institutionalized persons suffer this problem. The behavior can take many forms, with striking one's head against a wall a typical example. If uncontrolled, the behavior can produce severe injuries, blindness, and possibly even death. The obsessive and repetitive character of SIB bars all possibility for intellectual and social development.

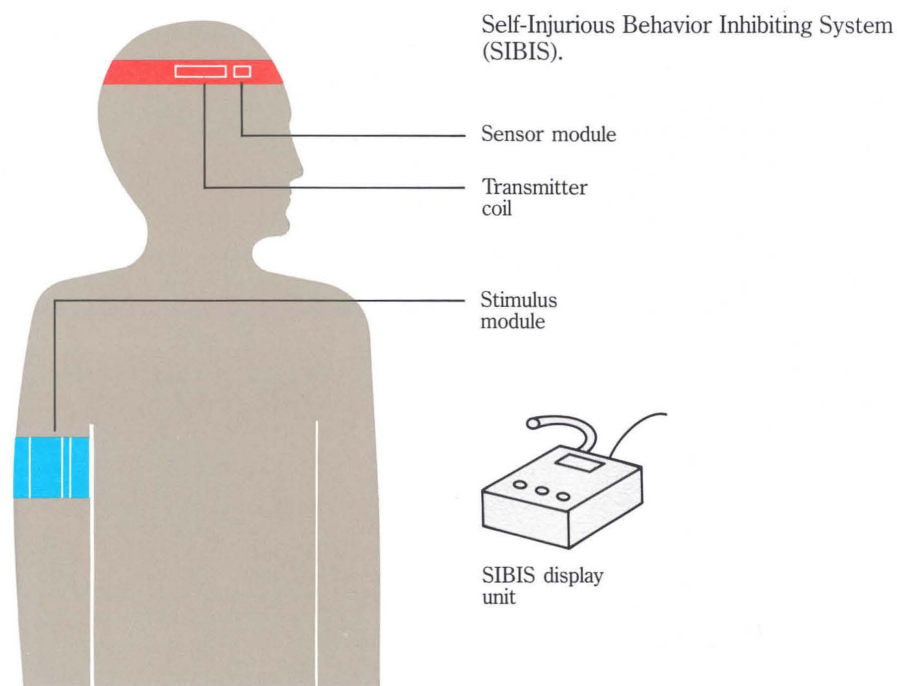
Many procedures have been used for the control of self-injurious behavior. The principal method is restraint, which offers no therapeutic benefit. Drugs can be effective but must be administered in such doses that all activity is curtailed. Behavioral modification procedures offer a real measure of hope but, in general, operate too gradually for practical use with severely retarded children. The most successful procedure involves the use of aversive electrical stimulation (shock) triggered

by an act of self-injurious behavior. Such stimulation suppresses the behavior almost immediately. The problem here is that existing equipment for administering the stimulation requires another person to be present to apply the aversive shock. The equipment itself is large, cumbersome, and frequently unreliable.

The NASA Technology Utilization Program is supporting the Applied Physics Laboratory of The Johns Hopkins University in the development and test of an improved system for inhibiting self-injurious behavior. This program was undertaken at the request of the American Foundation for Autistic Children. The objective is to develop a new method for administering the stimulation. This system will use aerospace technology and will make the aversive stimulation self-administering. A sensor module consisting of an accelerometer and a transmitter small enough to fit into an elastic headband will be used. This device could also be placed on the arm or other areas as desired. When a SIB

event is detected through an accelerometer signal, the sensor electronics will transmit a coded signal to the stimulation module. Upon receipt of the correct coded message the stimulation module will produce the appropriate aversive stimulation to the patient's arm. The system also will incorporate an event recorder to study the patient's behavior when using the device.

The advantages of SIBIS are many. It operates automatically and does not significantly restrict a patient's activities. The intervention of another person is not required. Finally, it offers hope for recovery and allows the social development of a child to continue.



Helicopter Medevac

Helicopters have played, and are projected to play, important roles in such public service activities as emergency medical service (EMS), search and rescue, law enforcement and public safety and disaster relief. In emergency medical service alone, studies show that in 1980 the annual death rate due to accident trauma was greater than 100,000 individuals. Trauma is estimated to cost U.S. society some \$87 billion annually according to Department of Transportation Statistics. With prompt, on-the-scene treatment and rapid transport to shock trauma centers, it is estimated that a 50 percent reduction in death and a substantial reduction in permanent disability and length of hospital stay, as well as substantial cost savings and gaining the use of the services from the injured, could be realized. This is a unique capability the helicopter has served and can serve even more effectively.

NASA has supported studies and workshops directed at identifying the uses, user requirements, benefits, and technology needs of helicopters serv-

ing the public sector. The studies show that the nearer-term technology development needs for various public service vehicles are very similar and are reflected in those for EMS helicopters. The 1981 EMS Workshop concluded that special action was needed to develop more effective EMS helicopters. It was recommended that NASA serve to bring the involved parties together to better define system needs and pursue the helicopter technology developments required.

Vehicles used for public service missions have historically been developed by the Department of Defense for military applications and have been utilized in the civil public sector with a minimum of modifications. However, the studies and workshops recommended that vehicles be specifically designed to meet the civil public service user requirements.

Recognizing this growing need, the NASA Technology Utilization Division and the NASA Ames Research Center are sponsoring an effort to identify those technologies that, if properly ap-

plied, could result in an improved public service helicopter. Working closely with both the U.S. helicopter and medical device industry, this program not only includes technology development in the helicopter airframe, but also addresses special onboard equipment needs such as improved portable medical diagnostic equipment.

As part of this project, NASA sponsored a special workshop in March 1984 entitled "Helicopter Medical Equipment Needs Workshop." The findings of this workshop will be used to develop special focus projects that address these equipment needs.



Ultrasonic technology, using sound waves just above the limits of human hearing, increasingly is employed in new medical procedures. An ultrasonic pulse, typically at a frequency of 10 to 20 MHz, is transmitted into the body from a clamped transducer. The emitted pulse moves through a coupling path, serving as a delay line to separate ultrasonic data from high frequency electromagnetic signals, before entering the skin to be characterized. As the pulse moves through the tissue, echo reflections are recorded. These echo patterns change as the signal is reflected from a different type of tissue, e.g., necrotic versus viable tissue. With ultrasonics, a resolution of approximately 0.1 mm can be achieved in soft tissue.

Ultrasound Determination of Burn Depth

The treatment of burn injuries is a major medical care problem. Each year, approximately seventy thousand patients in the United States receive intensive care for burns. Recovery can be significantly influenced by the treatment received. Full-thickness burns, those in which the entire dermal layer is destroyed, are treated through early removal of necrotic tissue and subse-

quent skin grafting. This minimizes the risk of infection, the major cause of death in burn victims. However, grafting is not the optimum procedure when there is only partial tissue destruction. Unfortunately, clinical judgments of burn depth based on surface appearance and tactile sensation are unreliable and imprecise. The appropriateness of treatment requires an accurate method of determining the exact depth of a burn injury.

A physicist at the NASA Langley Research Center developed a concept for determining skin burn depth using ultrasound. He noted that the acoustic impedances of burned dermis, viable dermis, and subcutaneous fat differ sufficiently to detect the interface between burned tissue and the underlying unburned tissue. With this measurement system, an early determination could be made of burn depth, allowing immediate excision of full-thickness burns and consequent reduction in mortality, leading to a more rapid and complete rehabilitation of the patient.

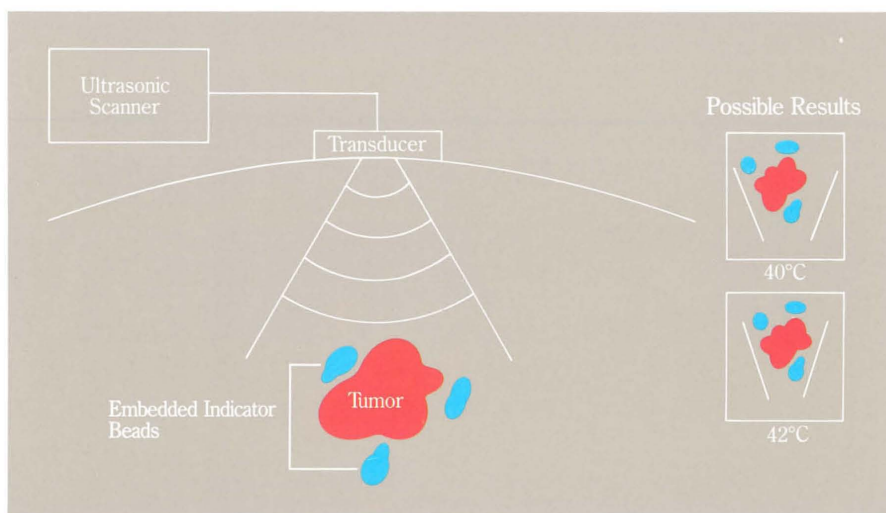
The Technology Utilization Officer at the Langley Research Center requested the assistance of the Research Triangle Institute Biomedical Applications Team in an evaluation of the ultrasound burn measurement sys-

tem. A team of medical clinicians has been assembled for this evaluation. The U.S. Army Institute of Surgical Research was selected as the primary collaborator. Approximately 225 seriously burned patients are admitted to this facility annually. Clinical trials here will examine the effectiveness of this measurement system and determine appropriate procedures for its use before the system is released to industry for marketing.

Ultrasonic Temperature Measurement in Cancer Therapy

Localized application of heat (hyperthermia) has been demonstrated to be effective in destroying malignant tumor cells while leaving normal cells intact. The destruction of malignant cells occurs because these cells have an inadequate blood supply and are unable to conduct away much of the applied heat. Microwave energy typically is used to provide the hyperthermia treatment.

The treatment of cancer with hyperthermia requires the temperature to be maintained within a narrow range of 43 to 44°C over a period of time, perhaps an hour or more. If the temperature falls, little cell destruction occurs; if it rises, normal tissue



destruction results. The success of hyperthermia as a cancer treatment has been limited to date due to poor techniques for monitoring temperature at the tumor site. Ultrasound, however, has the potential for providing long-term accurate temperature monitoring with minimum risk to the patient.

A technique, based on research in ultrasonics at the NASA Langley Research Center, may allow continuous monitoring of hyperthermia. This procedure uses an ultrasound probe system to monitor, at brief intervals, the melting of masses of selected lipids, or fat substances. Each lipid is refined so as to have a sharp melting point within the temperature range of interest. These contrast with natural body fat which is a complex mixture with no sharply defined melting point. Before treatment, the lipids are placed by injection in a tight pattern very close to the tumor. This pattern then is scanned by ultrasound periodically during the hyperthermia therapy. As lipid masses change from a solid to a liquid state, the ultrasonic echo pattern changes correspondingly. Thus, at any given time during therapy, a scan with ultrasonics will show which of the lipids are in the solid state and which are in the liquid state. The heat source then can be adjusted to maintain close

control over the temperature at the hyperthermia site.

The lipid masses are biocompatible and can remain in a patient for several weeks until naturally absorbed. They also can undergo multiple changes in state, back and forth from solid to liquid, before they become dispersed. They are thus available as temperature indicators during several sessions of hyperthermia.

The NASA Langley Research Center is coordinating the evaluation of the ultrasonic temperature monitoring effort. Tests to determine the ability of the system to measure phase changes in embedded indicator lipid beads are ongoing.

Intracranial Pressure Measurement with Ultrasound

Investigators at the Medical College of Virginia are working with NASA's Langley Research Center to explore the feasibility of utilizing ultrasound technology to evaluate traumatic head injuries. Measurement of intracranial pressure (ICP) is important in the management of the head injured patient. Currently, ICP is usually measured through direct placement of the cannula in the lateral ventricle of the brain. The cannula is coupled exter-

nally to a conventional strain gauge.

This invasive procedure has a number of disadvantages, including the risk of infection. A non-invasive technique for ICP measurement would be a contribution to the improved management of the head injured patient.

Scientists at NASA's Langley Research Center postulate that a change in intracranial pressure will effect a systemic change in tissue acoustical properties. It may be possible to measure these shifts in acoustical properties by non-invasive measurement at the skull using ultrasound. The shifts in acoustical properties could then be correlated with changes in ICP, thus providing the physician with a non-invasive technique for monitoring head injuries. The pulse-doppler technique proposed by the NASA scientists for measuring the alterations of acoustical properties and radial stress of the skull was developed initially for non-destructive testing of aerospace components.

Functional Electrical Stimulation

The classic demonstration of muscle contraction in response to electrical stimulation was done by the Italian physician Galvani in approximately 1790. At that time, interest centered on describing the physiological characteristics of nerve and muscle fiber. Since then, attention has shifted to practical uses for electrical stimulation techniques.

One of the first biomedical applications of functional electrical stimulation began in the early 1960's in a program to control peroneal palsy, frequently called "drop foot." In this program, functional dorsiflexion (foot lift) was obtained by means of currents generated by a portable electrical stimulator. Appropriate muscles were stimulated by electrodes placed against the external surface of the leg. At a later time, an implantable version of the device was used.

The success of the peroneal stimulator led to consideration of a multi-

channel device which would control more than one paralyzed muscle. A multi-channel system could be used in the support and rehabilitation of cases where full loss of limb function was involved.

The Veterans Administration Medical Center in Cleveland, Ohio, in cooperation with Case-Western Reserve University, has been working on a functional electrical stimulation system for the lower extremities. They have demonstrated that a computer-controlled multi-channel externally mounted stimulator can be used to make a lower-limb paraplegic stand and even walk a few steps. This represents a significant advance in the rehabilitation of cases with spinal cord involvement.

The current stimulation system consists of a rather cumbersome combination of a backpack control box, surface electrodes, force shoes, crutches and a maze of wires. The next logical step

in the development of stimulation technology is to produce a simplified control system which can be implanted in a patient. The National Aeronautics and Space Administration is collaborating with the Veterans Administration Rehabilitation Research and Development Service and the Case-Western Reserve University to develop an improved implantable device. NASA is providing packaging techniques and electronics reliability technology, taken from spacecraft development programs, to insure a workable design for a stimulation system.

The immediate goal of the collaboration effort is to develop a standardized implantable stimulator that can be used by researchers in many investigations of functional electrical stimulation on limbs, muscles and joints. The long-range goal of this program is to allow lower-limb paraplegics to stand reliably and to have a limited walking capability.

